



Telemedicine and Digital Medicine in the Clinical Management of Hypertension and Hypertension-Related Cardiovascular Diseases: A Position Paper of the Italian Society of Arterial Hypertension (SIIA)

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Abstract

High blood pressure is the leading cause of death and disability globally and an important treatable risk factor for cardiovascular, cerebrovascular and chronic kidney diseases. Digital technology, including mobile health solutions and digital therapy, is expanding rapidly in clinical medicine and has the potential to improve the quality of care and effectiveness of drug treatment by making medical interventions timely, tailored to hypertensive patients' needs and by improving treatment adherence. Thus, the systematic application of digital technologies could support diagnosis and awareness of hypertension and its complications, ultimately leading to improved BP control at the population level. The progressive implementation of digital medicine in the national health systems must be accompanied by the supervision and guidance of health authorities and scientific societies to ensure the correct use of these new technologies with consequent maximization of the potential benefits. The role of scientific societies in relation to the rapid adoption of digital technologies, therefore, should encompass the entire spectrum of activities pertaining to their institutional role: information, training, promotion of research, scientific collaboration and advice, evaluation and validation of technological tools, and collaboration with regulatory and health authorities.

Keywords Digital medicine · digital health · telemedicine · arterial hypertension · blood pressure monitoring

1 Digital Health and Digital Medicine

High blood pressure (BP) is the leading cause of death and disability globally and a major treatable risk factor for cardiovascular (CV), cerebrovascular, and chronic kidney disease. It is one of the most common reasons for a primary care visit, affecting about one-third of the Italian adult population, nearly 100 million Americans, and about 1.5 billion individuals globally.

Despite recent improvements in pharmacological and non-pharmacological treatments, BP control remains sub-optimal in the general population, with only 35-40% of treated hypertensive patients achieving the recommended therapeutic targets [1, 2].

Several technologies have been developed for automatically transmitting home BP monitoring (HBPM) to remote

databases, and more advanced technologies are becoming available to support the management of arterial hypertension, potentially leading to improved BP control at a population level.

The increasing attention to digital health technologies as practical tools to manage CV disease is reflected by the growing number of publications reporting the impact of these technologies on the patient's quality of life and CV risk factors management [3]. The increasing request for rapid implementation of digital health devices in clinical practice stimulates regulatory authorities and scientific societies to release specific recommendations guiding their development, validation and clinical use.

Digital health encompasses all applications of digital technologies in health management and healthcare. According to World Health Organization (WHO), a digital health intervention involves applying digital technology to achieve specific health objectives [4]. Within the broad area of this definition, the taxonomy includes: (1) mobile

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phone applications (apps), smartwatches, tablets and more advanced wearable devices (m-Health); (2) medical technologies, including telemedicine platforms and instruments that allow sharing of clinical data among patients and treating physicians; (3) innovative medical devices with high-quality hardware and software, that allow an integrated analysis of large datasets (Fig. 1).

All these facilities have been developed to support BP management while improving the quality of life of people affected by arterial hypertension (Table 1) [5–8]. Although attractive, these approaches also carry potential threats, including the possible reduction in the quality of health care, non-compassionate or delayed medical interventions, inadequate privacy protection and the use of non-scientifically validated sources of information.

2 Digital Medicine and High Blood Pressure

Digital health relies upon providing healthcare services at a distance [4]. As such, it involves several activities, including storing, retrieving, sharing and exchanging health data through information and communication technologies (ICT). The development of ICT, with the continuous expansion of high-speed, large-capacity internet network connections and dissemination of mobile devices, has revolutionized medicine, enabling remote medical care through internet-based platforms.

On Apr 29 2022, the Italian Ministry of Health released a public document entitled "Digital model for the implementation of digital homecare", in which digital health technologies

are recognized as critical instruments to achieve one of the fundamental objectives of Italy's recovery and resilience plan: the improvement of medical assistance in each Italian region. Some of the main instruments used in digital medicine, especially those supporting homecare, are potentially useful to improve the management of patients with hypertension. These are televisit, medical teleconsultation, specialist teleconsultation, telemonitoring and digital therapeutics.

1. **Televisit** involves a real-time interaction between the patient and physician. A televisit constitutes a medical act during which the physician interacts with the patient, suggesting adjustments to the antihypertensive treatment, prescribing further exams or reviewing results already available. The provider could be a general physician or a specialist. The user is the patient, the caregiver, or anyone involved in patient management at home. The preferred method to deliver a televisit is via video call, and the outcome of the visit might consist of a medical report or a recording.
2. **Medical teleconsultation** relates to an interaction between two or more physicians (including general practitioners and/or two or more specialists) involved in managing hypertensive patients. Such interaction could be developed in real-time or asynchronously. The presence of the patients is not mandatory but might be considered. When the patient is involved, the preferred delivery modality is a video call. A specialist teleconsultation is usually asynchronous, and its outcome is a written clinical report stored in the patient's electronic health record.

Fig. 1 The different products of digital medicine have different purposes and relationships with mobile-Health devices

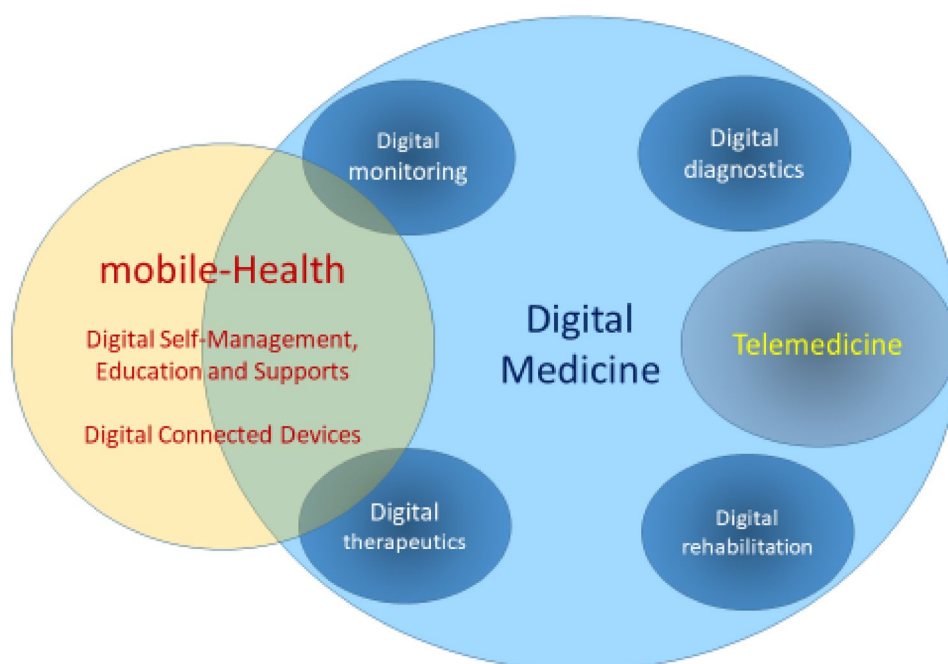


Table 1 Digital devices and technologies: requirement for validation and through clinical research and regulatory authorities

Definition	Health digital interventions include technologies, platforms, and systems that engage consumers in lifestyles, wellness, and health-related purposes; capture, store, or transmit personal health data and support health-related activities	Digital Medicine includes software and hardware products based on clinical evidence that measure and/or intervene in the service of human health	Digital Therapeutics deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease
Clinical trials	In most cases relates to applications or wearable devices that are freely marketed and do not require clinical trials	Validation through clinical trials is required for all Digital Medicine products	Clinical trials and outcome results in the context of medical practice are required
Regulatory approval	These products do not fall within the regulatory definitions of a medical device and do not require regulatory oversight	Regulatory oversight requirements are different. Digital Medicine products classified as medical devices require clearance or approval	Digital Therapeutics must be evaluated, approved or certified by appropriate regulatory bodies to support risk, efficacy and intended use claims

3. **Telemonitoring** consists of the detection and transmission of BP-related parameters recorded at home. It requires dedicated technologies for data recording, transmission and delivery, which are usually applicable to BP monitoring devices, as well as secure platforms for data storage and review. Telemonitoring platforms can provide information on treatment adherence and generate alarms related to changes in the patient's clinical conditions. It does not require real-time interaction between medical staff and patients.
4. **Digital therapeutic** refers to an emerging branch of medicine which utilizes technology-based software algorithms or apps to facilitate BP control, whose efficacy is still under evaluation.

3 Evidence on the Potential Benefits Derived from the Application of Digital Medicine in Managing Arterial Hypertension

Digital medicine should facilitate the management of arterial hypertension, ensuring more effective, interactive and integrated monitoring of its evolution and treatment. Validation is an essential requirement of tools used in digital medicine, as it confirms that the acquired parameters are securely stored, reliable and usable for monitoring the disease evolution and its treatment. Designing clinical trials to validate new technologies is, therefore, mandatory to expand the utilization of digital medical devices and platforms.

In the last two decades, there has been a rise in clinical studies evaluating the effectiveness of digital medicine in managing arterial hypertension, mainly based on the acquisition of home BP values through telemedicine platforms [9]. HBPM facilitates tailoring and personalization of BP-lowering therapies as it enables the acquisition of more reliable BP values, also improving therapeutic adherence to prescribed medications. Consequently, HBPM has been shown to improve BP control, and international scientific societies strongly recommend and endorse its use [10, 11].

In recent years, several improvements have been obtained in the accuracy of automatic and semi-automatic validated devices for HBPM. Furthermore, several technologies have been developed for automatically transmitting the HBPM data to cloud databases, enabling simplified sharing of this information with specialist physicians or general practitioners.

Studies based on HBPM-based telemonitoring have shown that the use of digital tools is associated with a limited but sustained reduction of BP values compared to standard BP management approaches, mainly when physicians, pharmacists, nurses or trained patients are in charge of the data collection [12–20]. More significant benefits have been

obtained when digital interventions are aimed at a broader reduction in the patient CV risk burden [21, 22]. Under this perspective, wearable instruments (m-Health) that detect patients' habits and levels of physical activity might be used to set up and monitor more complex and personalized interventions. Indeed, several wearable instruments may retrieve important information on the patients' lifestyles influencing CV risk. For instance, counting a low number of daily footsteps may characterize a sedentary lifestyle and could be used to refine the calculation of the patient's CV risk [23]. Preliminary results from clinical trials indicate that m-Health positively impacts BP control [24, 25], promoting patient engagement, and interaction with treating physicians and nurses [26, 27].

The recently published Home and Online Management and Evaluation of Blood Pressure (HOME BP) trial [16], including 552 hypertensive patients, has documented that a digital intervention based on supervision and titration of antihypertensive treatment and patient's selected lifestyle modifications led to a mean reduction in systolic BP of -3.4 mm Hg (95% confidence interval -6.1 to -0.8 mm Hg) and in diastolic BP of -0.5 mm Hg (-1.9 to 0.9 mm Hg) compared to the control group during a follow up of 1 year. Remarkably, there were low incremental costs related to the adoption of the digital intervention compared to the standard approach, highlighting the economic feasibility of integrating digital interventions in a primary care setting.

Positive results were also obtained in the HERB Digital Hypertension 1 (HERB-DH1) pivotal trial [28], using a new interactive smartphone apps designed to support users in pursuing consistent lifestyle modifications to reduce BP (the HERB system). The digital intervention was delivered by the HERB app that, by analyzing user inputs related to personality, behaviours and BP control, suggests medically validated, non-pharmacological lifestyle and behavioural changes (including salt restriction, control of body weight, regular exercise, and alcohol restriction) tailored to the patient's characteristics and specifically designed to reduce BP, according to the recommendations for managing hypertension published by the Japanese Society of Hypertension. Physicians can also stimulate the patients to use the app daily (e.g. watching educational lectures in the app developed to increase awareness of the importance of BP management).

A recent systematic review and meta-analysis of 18 randomized controlled trials assessing the potential impact of application-based telehealth programs on BP optimization showed that 86% of individuals randomized to the app-intervention group had a more significant systolic or diastolic BP reduction than the control group. Nevertheless, mean change effect sizes were modest (1.1 for systolic BP and 0.98 for diastolic BP), and there was a high level of heterogeneity

between studies, calling for caution in interpreting the study findings [9].

Although digital health-related interventions have documented their effectiveness in improving hypertension management, several problems remain to be addressed, including the frequent use of non-validated/inaccurate devices and the presence of social, cultural and educational barriers to using these technologies. Furthermore, some applications might suggest adopting lifestyle changes that are non-scientifically proven. A 2021 position paper by the Working Group on Blood Pressure Monitoring and Cardiovascular Variability of the European Society of Hypertension [29] recognized that these issues should be resolved before endorsing the systematic adoption of digital solutions in CV prevention. Many randomized controlled trials are ongoing. Among these, the CV-PREVITAL study should be mentioned, given it represents the largest trial in the field, with an expected enrollment goal of 80,000 healthy individuals referred to general practitioners, pharmacies, or hospitals. This primary prevention trial aims to assess the cardiometabolic effects of an m-Health intervention in an adult population [30].

4 Validation of Digital Instrumentation for Blood Pressure Monitoring

The BP monitors used in telemedicine can be the same as those used in clinical practice. Depending on the telemonitoring platform, they might simply acquire and register BP values (that the patients must subsequently communicate to the physician) or be equipped with Bluetooth or Wi-Fi connections, enabling direct transmission of BP values to the patient's electronic medical record. In any case, the instruments must receive validation for accuracy, in agreement with protocols designed by scientific societies and standards (ISO 81060.1-2) [31–34]. Monitors must be able to provide reproducible data and capture clinically relevant events [34].

Recent technological advancements have led to the development of new digital instruments for cuffless blood pressure measurement at home. These are based on different technologies, including oscillometric measures at the wrist, applanation tonometry, photoplethysmography, pulse transit time, or other techniques like, for example, finger-wearable monitors that offer the potential for continuous BP monitoring [35]. Standards to be met for proper validation of cuffless devices have been released (ISO 81060.3-2022, IEEE P1708), and hypertension scientific societies have provided recommendations to ensure adequate and controlled development of this rapidly evolving field of medical technology [31, 36]. It should be emphasized, however, that the few cuffless devices tested in validation studies have demonstrated only moderate concordance in the measure of BP values compared to reference monitors. Differences in the validation protocols limit the

opportunity to compare different studies and the accuracy of the investigated devices [37, 38]. Moreover, the relationship between BP measures acquired with cuffless devices and hard CV outcomes has yet to be fully established, and international recommendations regulating the validation process are not available [39].

Other devices that require scrupulous evaluation of their safety and effectiveness through clinical trials are digital instruments and application-based telehealth programs that not only provide monitoring of haemodynamic parameters but also suggest or guide the patients in managing the disease, as in the case of digital therapeutics. For these devices, the registration process should align with that required for new drugs and their commercialization should comply with the roles for selling of medical devices for human use established by the regulatory authorities in EU (Regulation EU 2017/745) and USA (Food and Drug Administration. Policy for device software functions and mobile medical applications; guidance for industry and food and drug administration staff: <https://www.fda.gov/media/80958/download>). Apart from these recommendations, no specific legal regulation currently exists to regulate the growing field of digital therapeutics. The European Medicine Agency, the European Commission and national health authorities are exploring regulatory intervention, while the FDA Digital Health Center of Excellence has provided regulatory advice (<https://www.fda.gov/medical-devices/digital-health-center-excellence>) [39].

5 Patient Engagement and Potential Inequities

Telemedicine and digital medicine may become important assets in improving the population's health, as they can support public health systems in accomplishing their primary goal of ensuring equal and timely access to healthcare services and personalized treatments [7, 40]. These objectives appear achievable through further development of remote clinical monitoring tools and improved experience in their appropriate use. A clear example of the potential advantages achievable with the broader use of remote monitoring devices has been offered by the COVID-19 pandemic, when telemedicine and digital medicine platforms have allowed effective management of arterial hypertension and other clinical conditions through patient-physician remote interactions [41, 42]. While during the COVID-19 pandemic the adoption of remote monitoring platforms has been forced by the emergency and has often been managed by single physicians with limited training, there is evidence that telemonitoring interventions are more effective when handled by multidisciplinary teams or healthcare organizations, including administrative figures, physicians, and other healthcare professionals. Blood pressure reduction obtained

by electronic health technology is more significant if the intervention is intensive, well-accepted by the patients, applicable to large populations, and partially replaces the usual model of care [43, 44].

The patient characteristics and acceptance of the intervention are also relevant aspects that should be considered to ensure equality in the delivery of digital health [45]. The level of education and digital skills represent potential barriers to using digital health devices or delivering digital interventions, particularly for patients requiring closer monitoring of the disease or its treatment, such as older patients and those experiencing unfavourable social conditions [46–48]. Shared decisions on treatment and access to electronic medical records may improve the outcomes of the intervention [36, 49].

6 Tailoring Digital Health Interventions to Overcome Potential Issues and Inequalities in the Management of Hypertension

Digital medicine can reduce inequalities in the management of arterial hypertension due to environmental or patient-related factors. In disadvantaged geographical regions, such as those with an extreme dilution of healthcare services or unfavourable orography, digital medicine may have a significant role in integrating healthcare data acquired in different settings, minimizing the fragmentation of care. A remarkable example is the "Campania Salute Network" (CS), a healthcare organization created at the Federico II University, Naples, Italy in 1998. The scope of the network is to improve BP management and overcome healthcare system deficiencies in the Campania Region (Italy) through the large-scale implementation of ICT [50]. The CS network involves 23 outpatient hypertensive clinics distributed in different community hospitals of the Campania Region, 60 randomly selected GPs uniformly distributed in the same area and the Federico II University Hypertension Clinic (as coordinating center). Clinical data collected at each visit are shared between healthcare professionals via text messages (SMS) or e-mails. Peripheral units (GPs and community hospital outpatient hypertensive clinics) manage hypertensive patients with a low-risk profile. In turn, the coordinating center reviews high-risk hypertensive patients and cooperates with the peripheral units in optimizing the treatment and organizing specialist evaluations where needed (i.e. monitoring the progression of HMOD and associated diseases). Information about patients is shared within the medical team through online access to a remote web-based database. The patient is at the center of this organization, as it should periodically communicate the home BP values via SMS to the platform. If the values are out of range,

the patient is automatically invited by a pc software to contact the center to revise his antihypertensive therapy [51]. A measure reflecting the capacity of the CS to support the delivery of care by the national health service is provided by the rates of BP control and reduction of the risk of fatal and non-fatal major CV events achieved in the Campania Region in 2016, which were the greatest in Italy [52, 53].

Beyond the simplified integration of healthcare services, another advantage related to the application of digital medicine in the field of hypertension relies on the use of telemonitoring systems that can minimize inequalities in the management of disease, potentially deriving from temporary or persistent illness. The SARS-CoV2 pandemic has shown the advantages of using telemonitoring platforms in managing patients who tested positive for the viral infection, in whom telemonitoring of vital parameters has not only informed on the BP control but also supported the distal management of the infective disease [54, 55]. Another example is provided by patients recovering from major surgery, whose limited mobility and concomitant pain or stress might preclude access to healthcare facilities while affecting the acquisition of reliable BP values [56, 57]. Telemonitoring has been used in this setting to optimize BP control and detect post-operative complications [58].

Telemonitoring also has considerable utility in the home management of frail patients with multiple chronic diseases [59, 60]. In this setting, the concomitant presence of cognitive or visual impairment might complicate the use of digital tools. However, such barriers can be overcome using devices tailored to the patient's clinical conditions and digital skills. For example, in patients unable to use e-mails or other ICT platforms, physicians can use telemonitoring systems that directly transfer home-acquired BP values to the patient's clinical records, minimizing patient involvement [60]. Similarly, video supports, voice assistants or smart speaker technologies embedded in remote BP monitoring systems can guide patients with cognitive or visual impairment on the correct use of the devices [61–63]. The same vocal and/or visual aids might be used to remind the right time and type of antihypertensive medication, potentially resulting in improved treatment adherence, BP control and reduced risk of treatment-related complications [64, 65]. The adoption of easy-to-use tools and appropriate training programs for the patients and their caregivers remain, however, essential requirements for the proper implementation of digital medicine in the management of frail patients.

Digital health and, more specifically, telemonitoring systems can also be used to confirm a new diagnosis of hypertension, particularly in patients with a suspected white-coat or masked hypertension [29, 31, 66–68]. In these cases, an initial in-person visit is recommended to detect potential signs of hypertension-mediated organ damage or secondary hypertension [31], as well as to establish a meaningful

relationship with patients [69], educate patients on self-management of healthy lifestyles and guide patients through the appropriate HBPM technique [70]. Thus, digital health-guided HBPM may be used to confirm the diagnosis of specific hypertension phenotypes.

Finally, patients with substantial elevation of BP (grade III hypertension) during a clinical assessment and/or requiring significant changes in the antihypertensive therapy can have significant advantages in using systems of remote BP monitoring. In these cases, telemonitoring allows the patient's BP profile to be confirmed more accurately and rapidly than repeated outpatient visits, facilitating a faster and safer optimization of BP control and treatment.

A summary of the potential issues and solutions in the application of telemonitoring tools in the management of patients with elevated blood pressure is provided in Table 2.

7 Digital Technology: Expectations, Ethical Issues and Risks

The extensive transformation resulting from the use of digital technologies in the management of chronic diseases requires careful consideration of the individual right to privacy and the adoption of all possible security checks to ensure its protection [71]. Indeed, the acquisition and management of personal and health data by platforms of digital medicine require processing sensitive data through electronic instruments. Thus, similarly to any other system dealing with personal, health-related data, these platforms should respect the fundamental right to data privacy and protection. Specific laws are available to regulate the management of these data at the Italian (legislative decree 196/2003) [72] and European [73] level. Full respect for these regulatory references does not exhaust the ethical roles of physicians, as patients should also be informed on each step involved in processing their sensitive data. Also, the use of digital platforms, particularly those that enable remote monitoring, should not preclude the patient's right to be informed and to have enough time to reflect on the potential risks and benefits of different diagnostic and therapeutic options. A remote patient-to-physician relationship might complicate the communication of negative results or reduce the time to reflect on the initiation of challenging treatments. Therefore, telemedicine requires specific attention by physicians to the effectiveness of their interactions with the patient. Concomitantly, the use of digital medicine platforms, particularly telemedicine, also involves a different disease approach by the patients. Indeed, digital medicine solutions often assume a more active contribution of the patients in managing the disease, given they are generally involved in the remote acquisition of regular and reliable data. Consequently, the patient is empowered to take control

Table 2 Potential issues and solutions related to the use of remote blood pressure monitoring (RBPM) systems in different clinical settings

Patient phenotype	Potential issues	Potential solutions
Patients with a possible new diagnosis of hypertension	Limited opportunities for detailed physical examination by the care provider and for voicing potential concerns by the patient Limited confidence of the patient in the treating capacity of the care provider Limited training on the best RBPM method	In-person or, if not possible, video-based initial evaluation Physician, assistant or nurse should guide patients through appropriate BP self-measurement technique
Patients with limited mobility due to concomitant acute or chronic diseases	The accuracy of RBPM might be affected by the development of complications (i.e. post-operative atrial fibrillation)	Use RBPM devices that allow a multiparametric assessment of the patient, simplifying the detection of potential complications
Older and/or frail patients	Limited use and inaccurate use of RBPM due to: Cognitive impairment Limited digital skills Visual impairment	Use of RBPM devices that: Enable direct transmission of the recorded BP to the health care provider Use RBPM systems equipped with voice or videos aids guiding patients on the correct use of the device
Patients with suspected white coat hypertension or masked hypertension	Inaccurate BP values obtained from RBPM due to: Anxiety, emotion, psychological stress Incorrect home BP recording technique	Educate the patient on the importance of home BP monitoring Use of RBPM systems equipped with voice or videos aids reminding the appropriate BP self-measurement technique
Patients with grade III hypertension at the outpatient visit	The accuracy of RBPM might be affected by: Patient anxiety and psychological stress during BP recording Insufficient number of remote BP acquisitions (patient concerned about finding elevated BP values) Selective under-reporting of high BP readings	Use of RBPM devices that: Enable direct transmission of the recorded BP to the health care provider Physician, assistant or nurse should provide extended education on the importance and appropriate technique of BP self-measurement
Patients requiring a radical change in therapy	Insufficient number of BP measurements that do not provide accurate information on the BP control achieved with the new treatment Limited opportunity for avoiding potential side effects emerged after the initiation of the new treatment	Provide patient education and feedback on target BP, normal BP variability, and actions to take if BP is too high or too low or in case of side effects RBPM devices that enable rapid interaction with the health care provider to adjust treatment dosage and schedule
Patients who could benefit from greater involvement in the disease management	The accuracy of RBPM might be affected by: Insufficient number of BP measurements Selective under-reporting of elevated readings Failure to relay BP readings	Use of telemonitoring systems that transfer the acquired BP values directly to the health care provider

of the illness, its management and its treatment. While these aspects are generally associated with improved control of the risk factors, an excessive self-management of the disease could lead to the patient's adoption of therapeutic or diagnostic decisions without consultation with the physician [74, 75]. A summary of opportunities, challenges and expectations related to the introduction of telemedicine and digital medicine in health systems is depicted in Table 3.

8 Regulatory Matter

As of May 26, 2021, the new EU Regulation 2017/745 on medical devices [76] is fully effective throughout the EU. This document introduces important changes to the roles guiding the development and marketing of new medical devices, increasing their expectation for safety and introducing the new requirement of "performance". The document redesigns the tasks and responsibilities of the selling companies, who are now requested to play a much more proactive role in ensuring more rigorous oversight of the medical device throughout its entire life cycle. It has strengthened the importance of maintaining a clear connection between the clinical validation carried out by the manufacturer, the technical documentation of the medical device, its intended use and the information provided to the public about the product. The same regulation has also intensified the post-market surveillance and vigilance requirements, increasing the controls carried out by Notified Bodies and Competent Authorities.

For EU marking, software/apps equipped to acquire potentially relevant medical information should comply with the same regulations as any other traditional software/apps and are divided into several classes. Tools above Class I require the certification of a notified body before marketing. Independently of their class, software/apps should

have a technical dossier, which must be kept available to the authorities and registered on the European portal EUDAMED.

Telemedicine platforms may be considered medical devices, depending on their functionality and intended use. After the publication of the State-Regions Agreement on National Directions for Telemedicine in 2020 [77], the qualification of a software/app as a medical device depends not only on its intended use but also on the "functionality" of the software itself. More specifically, if the software processes, analyzes, creates, or modifies medical information, it qualifies as a medical device and should be certified as such, while such a certification is not required if the device only acts as data storage.

Similar concepts are included in the annex to the recent public-private partnership tender for the telemedicine platform [78]. According to this document, a certification as medical device is not required for every telemedicine platform before EU marking. However, attention must be paid to the functionality of the software. If the software/app develops analytics logic that, by applying artificial intelligence algorithms, can produce smart suggestions supporting health care professionals in the identification of more effective care solutions, then the software module capable of proposing these suggestions is considered a medical device, and should be marked according to the new EU Reg. 2017/45.

9 Integration of Telemedicine and Digital Health Within the National Health System: Remuneration and Cost-Sharing, Data Protection and Legal Issues

The integration of telemedicine and e-health systems into clinical practice is encouraged by World Health Organization (WHO), which also provides detailed indications

Table 3 Integration of digital medicine into health care systems: opportunities, challenges and potential risks

Opportunities	Challenges	Risks
Availability of effective and continuous medical support for the entire population through communication technology	Costs and reimbursement Digital divide in the population	Inadequate funding from health systems Lack of equity due to poor literacy and digital divide within the population
Timely recording and evaluation of clinical data	Data protection throughout the digital communication system	Lack of privacy, leaks and failure in data protection
Improved doctor-patient communication	Validated instruments. Scientifically proven medical advice and data recordings	Poor and non-qualified medical advice. Not scientifically proven information
Integration into the health care systems	Platforms, regulation and training of health personnel	Inadequate technical support and training to health personnel. Lack of involvement of health personnel in planning and decision making
Increased equity in the health care systems	Patients' engagement and information. Technical support and users' training	Exclusion of socially deprived and fragile persons

on areas of application and recommendations for local implementation. According to WHO, one of the long-term strategic objectives is to "establish and implement policies regarding practice, payment and accreditation for delivering integrated health services powered by digital solutions" [79]. While European Countries have implemented the EU recommendations of 2008, the integration of telemedicine into their healthcare systems remains limited, and barriers to the delivery of telemedicine have not been removed [80]. In the guidelines enacted in 2022 by the Italian Ministry of Health, the implementation of telemedicine in the primary care setting is regarded as a tool to strengthen home services and reduce hospital admissions, particularly for frail patients with chronic diseases [77]. In December 2022, this was implemented by a ministry decree transferring responsibility at regional and local levels, while the Ministry of Health is entrusted with the direction and creation of nationwide telemedicine platforms and data management systems [78]. In hospitals that have authorized televisits and telemonitoring for patients with hypertension, these activities have been fully integrated into the pathways of patient care, ensuring remuneration for health professionals and reimbursability for the patients. In these settings, the patient's data acquired and shared during the televisits or telemonitoring are managed by the informatics infrastructure of the hospitals and specific protocols have been developed for the collection of consent and secure exchange of sensitive information. In turn, telemedicine and teleconsulting protocols are not yet structured and supported by safe distal communication systems in the primary care setting. This exposes the clinical activity to risks related to shortcomings in data storage and protection, unclear roles and the use of non-validated tools in clinical monitoring and doctor-patient communication [31, 55].

10 The Role of Scientific Societies

International and national health regulatory authorities prompted initiatives to improve the use of digital health within the national health systems. The WHO initiative addresses the role of new health technologies by analyzing the evidence supporting digital medicine in specific areas including telemedicine, offering a scaffold on which to build intervention [7]. The International Society of Hypertension and the European Society of Cardiology are advising on the use of medical devices and protocols for BP monitoring using telemedicine [31]. Opportunities and challenges are being defined [36, 81–84].

The role of the Italian Society of Arterial Hypertension (SIIA) in relation to the fast-progressing digital

technology encompasses the whole spectrum of activities that attain its institutional role: information, training, research promotion, scientific collaboration, scientific advice, evaluation and collaboration with regulatory and health authorities.

These activities therefore include:

- Information to increase public awareness of opportunities and limits of digital devices and applications for self-management of BP, as well as training on telemedicine and digital medicine as tools in clinical practice and research for hypertension specialists, health personnel and expert patients.
- Evaluation of digital devices and applications and promotion of collaborative research and interaction with public institutions and start-ups or companies active in the field of digital technology.
- Cooperation with international scientific societies and regulatory authorities to reach clear definitions (and implications) of either home BP telemonitoring systems or home BP monitors (wearable or not) for improving hypertension management and control.
- Definition of standard requirements for home BP monitoring and telemedicine in hypertension, including number and variability in BP measurements in relation to the technical characteristics of BP monitors (automatic, semi-automatic), quality of distal transmission and integration with automated or manual data acquisition.
- Promotion of clinical trials for clinical validation of BP systems and monitors.
- Apply new technologies of data acquisition and analysis in clinical trials involving the treatment of hypertension.

The Society should anticipate and give advice on the implications of digital technology for daily clinical management of arterial hypertension and CV risk and cooperate with regulatory authorities in the definition of rules on privacy protection. The available evidence on digital medicine should be incorporated into guidelines.

11 Conclusive Remarks and Perspectives

Digital technology is fast developing and is expected to gain a key role in managing arterial hypertension, allowing more effective disease monitoring and better drug utilization. The potential benefits of digital health require advice, guidance and promotion by scientific societies. This can be accomplished through active participation in research and cooperation with health and regulatory authorities. Validation of digital devices and apps supporting the

management of hypertension is crucial and requires the contribution of hypertension specialists.

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Declarations

Conflict of interest No conflict of interest to declare.

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