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Home blood pressure measurement and digital health: communication technologies create a new context

Nicolas Postel-Vinay^a, Guillaume Bobrie^a, Sébastien Savard^b, Alexandre Persu^c, Laurence Amar^{a,d}, Michel Azizi^{a,d}, and Gianfranco Parati^e

Ambulatory blood pressure (BP) monitoring is encouraged by all international guidelines for the management of hypertension. Home BP monitoring is the preferred method of the patients. Automated BP devices with remote data transmission have been repeatedly shown to be useful in improving hypertension control in the frame of clinical trials on telemedicine. Recently, new technologies have created a new context. Despite the important number of smartphone apps devoted to BP developed these last 10 years, only two BP monitoring apps refer to the European Society of Hypertension (ESH) Guidelines and have been published in peer-reviewed journals: Hy-Result and ESH CARE. At present, the absence of close collaboration between start-up engineers and healthcare professionals is a risk for patient safety. Therefore, health professionals must become actors in the so-called digital health revolution.

Keywords: clinical decision support systems internet, E-health, healthcare costs, home blood pressure measurement, hypertension, M-health, self-care, self-measurement, telemonitoring

Abbreviations: AHT, arterial hypertension; BP, blood pressure; HBPM, home blood pressure measurement; ICTs, information and communication technologies

Given the continuous progress in computing science and informatics, the question is to what extent might the new solutions proposed by information and communication technologies (ICTs) facilitate or improve home blood pressure measurement (HBPM) implementation in the daily management of patients with hypertension. Although the earliest telemedicine experiments involving the remote transmission of self-measurement results were performed as early as the 1990s, mobile health technologies that connect blood pressure (BP) monitors to smartphones purchased by health consumers have been available for approximately 5 years. Despite the paucity of scientific data demonstrating the relevance and usefulness of e-health solutions, such techniques are now increasingly available and will play a progressively more and more important role in the management of chronic diseases, including hypertension [1–4].

HBPM is now encouraged in all international guidelines for the management of arterial hypertension (AHT) [5–8]. It

identifies individuals with white-coat hypertension or masked hypertension [7]. It is associated with a more exact and more precise assessment of cardiovascular prognosis than clinic BP measurement [8–11]. It empowers patients in their long-term disease, especially in cases of resistant hypertension or of high-risk individuals [5,12,13]. Its use improves BP control [14–18].

Reliable, easy-to-use, automated oscillometric BP devices have been available since the mid-1980s. HBPM is the method preferred by patients [19], when compared with alternative measures such as ambulatory BP monitoring. Its use has been increasing over the years [20] with HBPM being now adopted by a high percentage (40–60%) of hypertensive individuals [21,22]. In daily practice, however, the clinical benefits of this approach may be limited by inadequate patients' adherence to the recommendations on HBPM use in clinical practice provided by available guidelines (e.g. failure to observe the minimum number of measurements per day or the minimum number of days per measurement cycle) or by errors in HBPM data storage transmission [21,23,24]. In addition, many clinicians are unaware of the different target BPs recommended for home or clinical settings. [5,24]. These different factors can lead to errors in the interpretation of the results.

HBPM requires appropriate performance by patients in relation to three sequential tasks: compliance with the measurement protocol; transmission of the results to physicians; and self-interpretation of the results in order to adapt their self-care approach (e.g. call their physician or titrate individual treatment regimen, when recommended to do so). In 1998–1999, several studies assessed the extent to which patients who self-monitored their BP were able to record their results reliably [25–28]. A pilot study in 2003

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invited the residents in Exeter (Devon, UK) to self-measure their BP using devices made freely available to them in public spaces, and were asked to refer to their general practitioner if their BP readings were above a preestablished threshold [29]. Acceptability was found to be high and the approach feasible. In 2005, a pilot study conducted with French general practitioners demonstrated the feasibility of self-adjustment of antihypertensive treatment by patients based on HBPM results according to a self-titration action plan set out in a handbook [30].

THE ACHIEVEMENTS OF TELEMEDICINE

Automated BP devices with remote data transmission have been repeatedly shown to be useful in improving hypertension control in the frame of clinical trials on telemedicine. However, given that telemedicine services in this field are generally not reimbursed by healthcare systems, home BP telemonitoring has very seldom been applied in routine practice. The difference in SBP and DBP in patients using automatically transmitted HBPM readings compared with usual care was -3.7 and -2.5 mmHg, respectively, in a meta-analysis of 23 randomized trials. It was also associated with a 16% improvement in the frequency of BP control [4]. This better performance is likely explained by the positive impact of the teletransmitted feedback on patient compliance and its effect in improving physicians' inertia. In 2010, McManus *et al.* [31] demonstrated the ability of adequately trained patients using self-BP monitoring to adjust their treatment when finding average home BP repeatedly above the target range.

As of now, few manufacturers are committed to marketing this technology into a viable and sustainable commercial product. This may be not only due, as already mentioned, to the lack of funding in general medical practice (at least in Europe), but also to the fear of interfering with medical decisions in case of inadequate patient training, as well as to the liability to potential errors and the difficulties in properly managing the privacy and security issues related to the remote transmission of sensitive data. Moreover, only a few BP monitors are currently able to remotely transmit BP readings to a server once users have logged on and identified themselves. It is up to users to inform their physicians and provide them with the codes that will allow them to access the self-measured BP data sent to a cloud. The organizational complexity of this method is an obstacle to its generalization to all patients with hypertension. Its use is hampered by technical costs (purchase of wireless BP monitors and software, maintenance of servers, hosting of health data, IT support) and by the professionals' fees (nurses and/or physicians) [32]. The initial experiences of remote BP monitoring have had also to face additional difficulties because of the additional work loaded on healthcare teams, physicians and/or nurses, who have to receive and analyse a great number of BP recordings, and to properly address abnormal results [33], without specific financial incentive to do so. In addition, it has to be recognized that, apart from specific medical conditions (e.g. BP monitoring in patients with heart failure, pregnancy, severe hypertension, organ transplant), there is little

need in daily practice for remote BP monitoring over prolonged periods.

Contributions made by the Internet, smartphones and new technologies

Patients can deliver HBPM readings to the physician without the need for wireless BP monitors. First and foremost, patients can simply bring their BP log to the physician in charge on the day of the consultation. Online data collection forms have been available for the last 15 years to automatically calculate mean SBP and DBP (not only overall mean but also separate morning and evening means), for example the calculator available on the *automasure.com* website since 1999 [34]. As early as in year 2007, a survey showed that the majority of patients trained to self-monitor BP were able to provide the results of three measurements twice daily over 3 days on a preprinted sheet (18 measurements in total), and almost one half had followed the advice to go online to calculate their mean [35]. One of the first programmes to deliver follow-up messages on mobile phone screens to diabetic and hypertensive individuals also appeared at this time [36].

Since 2010, many start-ups have developed a host of interactive digital tools that give the general population access to medical information and incentives to encourage better treatment compliance and to change their health behaviour. These new tools, accessible via the Internet or smartphones (apps), offer personalized feedback to patients [37]. However, very little is known about the reliability of many algorithms that remain a trade secret. A systematic review published in 2015 identified nearly 850 English-language smartphone apps devoted to BP (600 on 'Apple iTunes' and 250 on 'Google Play Store') [38]. An analysis of the first 107 smartphone apps for hypertension showed that, although intended primarily for the general population, only three had been developed by healthcare professionals, whereas others were turning smartphones into medical devices without any regulation by medical or governmental agencies, being mostly developed within the 'fitness' or 'wellness' world [39]. To our knowledge, no other systematic review of smartphone apps devoted to BP has been published so far.

When considering HBPM and new ICTs, four different aspects need to be discussed: those offering information on self-BP measurement and AHT (including online advice); BP calculators; apps storing readings captured by smartphone-connected BP monitors (originally via a wire and now by Bluetooth); and apps that estimate BP without a cuff-based BP monitor. As for smartphone-connected BP monitors, a technical analysis carried out by a government consumer association demonstrated that six BP monitors sold in France are deficient in several respects compared with the scientific recommendations: the sensors and their algorithms are not always valid or properly presented; the commercial information is sometimes inappropriate; the BP standards presented to users are not those recommended for HBPM; none of the algorithms associated with connected BP monitors specify BP targets according to the medical characteristics of patients (cofactors of cardiovascular risk and comorbidities) [40]. The novel, and most unusual, feature is the technical ability of smartphones to

TABLE 1. Apps designed in accordance with ESH guidelines (to our knowledge)

e-Health system in accordance with ESH guidelines	Presentation in a peer review journal	Validation study	Evaluation by users	Demonstration of potential benefits on patient's health outcomes	Demonstration of harm on patients	Endorsement by ESH	Citation by other authors
ESH CARE	Yes [48,49]	Yes [47]	None	Higher rate of control in users group ($n = 303$) than in the control group ($n = 298$) at 6-month follow-up) [47]	Unknown	Yes	None
HY-RESULT	Yes [45,50]	Yes [45]	More than 55% users declare that they will continue to use Hy-Result. Majority (98%) of patients found the app helpful to talk with the doctor about their HBPM readings [51,52]	None	Unknown	None	Yes [46,53]
Others ?	None in our knowledge	–	–	–	–	–	–

ESH, European Society of Hypertension.

display BP values without the use of a BP monitor! To achieve this, new, insufficiently validated algorithms process the signals picked up by the smartphone camera lens on which users place their index finger [41]. For example, engineers use cardiac seismography data (incorrectly called ballistocardiography) by placing the smartphone and its 3D accelerometers on the chest over the heart and measuring the pulse by simultaneously placing the finger on the smartphone's camera lens. The cardiac contraction causes a shock to the chest wall with a typical wave train. The inflow of blood into the finger induces a variation in light transmission, which, when integrated, generates a pulse wave. In the absence of external calibration by a cuff device, the performance of pulse transit time-based apps is disastrous [42]. It is possible to buy low cost 'smart wrist blood pressure watch monitors' on the internet and consumers are encouraged to 'monitor blood pressure anywhere at any time by advertisement'. In many instances, the method of estimation of BP is simply not available. Despite sometimes having a rational basis for their use in specific circumstances on occasion, cuffless BP measurements remain a technological challenge [43,44]. The various smartphone-based methods are notoriously inadequate and can lead to wrong decisions. As things stand, they should be formally discouraged. This, in fact, is now acknowledged by some of their designers (which was not initially the case), who marketed their apps more as 'games' to avoid involvement in a certification process that might penalize them. In the future, who knows what HBPM devices will come along?

New digital health solutions in accordance with the European Society of Hypertension guidelines

To our knowledge, only two BP monitoring apps referring to the ESH guidelines were fully described and published in peer-reviewed journals (Tables 1 and 2) [45–53]. They promote information on reliable HBPM methods and self-empowerment approach. One relies on text messaging with automatic interpretation of BP readings, the second is a platform accessible to physicians. We summarize their characteristics in the following section.

Automatic interpretation of home blood pressure measurement readings

Considering limited medical resources, e-education empowers millions of hypertensive patients under treatment to self-monitor their BP and gives many answers to patients being screened. According to this objective, we designed and validated an algorithm that automatically generates a computerized record of the self-BP measurement, while taking into account the patients' reported characteristics [45]. This Hy-Result software is available in two formats: as a web application freely accessible online or through certain connected BP monitors [54]. The purpose of this software is to help patients adhering to the scientifically recognized BP measurement protocol and self-interpreting their results in an effort to promote informative interaction with the physician, or to provide adaptive self-care practices via text messages or other media [46,47,55] (Fig. 1).

TABLE 2. App characteristics

	App for self are and self-empowerment	Manual insertion of the BP readings	Connection with a wireless monitor	Report for sending to the doctor	Online platform with access for health professional	Automated interpretation of home blood pressure readings	Storage of the data in the cloud
ESH CARE	Yes	Yes	Yes (in progress)	Yes	Yes	No	Yes (security granted)
HY-RESULT	Yes	Yes	Yes	Yes	No	Yes	No

BP, blood pressure.



FIGURE 1 The ESH CARE app. Screenshots showing some functions of the ESH CARE app. The app is designed to provide the user with educational material (3), to record BP measurements (4) and other physiological data, such as heart rate and weight, and to provide charts of BP values across time (5). Moreover, the app is able to store data on active medications and to provide reminders to the user (6). Adapted with permission from [47].

Hy-Result is a rules management system based on three considerations: current recommendations on the choice of BP thresholds; data from the scientific literature for the responses generated; and expert consensus for the formulation of messages in patient-friendly language. The automatically generated responses are based on an algorithm combining the patient's BP readings and characteristics. The algorithm classifies patients' mean BP values according to target ranges recommended by the European Society of

Hypertension (ESH). The threshold of 135/85 mmHg distinguishes controlled or uncontrolled hypertension in treated patients and normotension or hypertension in untreated patients. In patients with comorbidities, specific text messages are generated to indicate that a lower target BP could be more appropriate. The report uses colour-coding to facilitate communication with the patient [56]. The specific role of Hy-Result in the patient care must be clearly understood and the following three steps should not

be confused: classification of BP status; interpretation of BP readings; clinical decision-making. The Hy-Result algorithm concerns the first two steps and does not pretend to replace clinical decision-making, because it cannot take into account all the particular circumstances of each user. Accordingly, the Hy-result text messages make no diagnosis or treatment suggestions. As a precaution, each message states that the results must be discussed with, and validated by, a physician. This disclaimer does not contradict the fact that the software proved highly reliable in the validation study [45]. A user perception assessment is under way.

Online platform

A positive step was recently made by the Italian Society of Hypertension and the ESH who jointly developed a smartphone application whose content has a scientific validation, and which guarantees security and privacy standards when sending clinical data to a server or to the physicians in charge. This application, termed ESH CARE app, allows the user to collect his/her BP values, along with information on the ongoing drug therapy (also offering the possibility to the patient to receive reminders for pill intake by the phone itself). It also allows the transmission of the BP and heart rate values input by the patient to a dedicated website, wherein they are saved in an encrypted end-to-end form. These data may then be managed, organized and analysed by a dedicated patient's management system, allowing physicians in charge to use such information in the perspective of a better evaluation of patient's BP control, cardiovascular risk level and drugs intake, as well as for a more precise titration of drug prescription, with the final aim of achieving improved cardiovascular protection. Furthermore, specific sections of the ESH CARE app provide educational information for users on hypertension, cardiovascular risk and related complications such as atrial fibrillation. This app was also designed to promote self-empowerment of the patient aimed at stimulating his/her active collaboration in managing a high BP condition. The ESH CARE app is also aimed at favouring a better connection between patient and physician, thus improving patients' adherence to treatment and decreasing physicians' inertia, respectively.

A pilot study exploring the ability of this ESH CARE app combined with a dedicated patients' management system to be used by physicians was carried out in Northern Italy with favourable results [47]. Nine general practitioners randomized 690 consecutive uncontrolled hypertensive patients either to usual care or to this new management strategy. At 6 months, office BP control (BP <140/90 mmHg) was 40.0% in the control group, and 72.3% in the group randomized to use this modern approach, thus strongly supporting the favourable impact of this ICT strategy in hypertension management.

Additional larger scale randomized studies are now needed to further evaluate the impact on hypertension control by a management strategy based on the ESH CARE app associated with an online platform for patients' management, with the final aim of achieving a reduction in cardiovascular mortality and morbidity in hypertensive patients [48].

Innovation and the risk of unregulated consumer smartphone apps

The potential offered by new ICTs to improve HBPM is huge and raises issues of reliability, performance and costs that are yet to be resolved. Standard medical practice is undergoing major changes, such as the advent of online medical advice. Many questions remain unanswered: will the technology be able to meet healthcare patient's needs? Will it influence the use of unnecessary commercial products? Which regulatory framework will be able to keep pace with the speed of technological innovation? Care must be taken to ensure that inappropriate, uncontrolled medical information does not drive telemedicine and mobile health towards becoming an unregulated consumer practice. This is exactly what is observed with smartphone apps delivering BP measurement readings without the use of a BP monitor: their inaccuracy, potentially delivering normal results to one-third of hypertensive users, did not prevent one such app from being among the top 50 best-selling iPhone apps, with 950 copies sold at \$4.99 each day [42]. Nor can we trust in the online ratings of medical apps by both private companies and consumers [57]. At present, the risk of treating e-health as an entertainment remains real in the absence of close and early collaborations between start-up engineers and healthcare professionals. Guaranteeing patient safety is essential so the challenge is to combine imaginative innovation and rigour. Some believe that this synergy will be fostered by the introduction of consumer protection regulation, while others see the regulatory framework of the health sector as a brake on innovation, and even on the freedom of healthcare consumers to claim ownership of their bodies.

CONCLUSION

HBPM is encouraged in all international guidelines for the management of high BP, but new ICTs create a new context: patients will soon interact with algorithms that can be discordant with the guidelines or advice of their doctor. With their expertise of basic actions to achieve global BP goals, health professionals must become actors in the so-called digital health revolution.

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Conflicts of interest

There are no conflicts of interest.

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