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Original Article

OPEN

User engagement with home blood pressure monitoring: a multinational cohort using real-world data collected with a connected device

Jean-Simon Rech^{a,b,c}, Nicolas Postel-Vinay^d, Vincent Vercamer^e, Paul de Villèle^e, and Olivier Steichen^{a,b}

Objective: Connected blood pressure (BP) monitors provide reliable data when used properly. Our objective was to analyse the engagement of real-world users with self-measurements.

Methods: We included adult first-time users of a connected BP monitor from July 2019 to March 2021. They were categorized as persistent users if they continued to use the device between 311 and 400 days after inclusion. We defined a criterion to analyse the timing of selfmeasurements: at least 12 measurements performed within three consecutive days, at least once every 90 days. Persistent users were clustered by state sequence analysis according to the consistency of their BP monitor measurement timing with this criterion during 1 year of follow-up.

Results: Among the 22177 included users, 11869 (54%) were persistent during the first year. Their use was consistent with the timing criterion 25% (median) of this time (first and third quartiles: 0%, 50%) and four patterns of use were identified by clustering: 5215 persistent users (44%) only performed occasional sparse measurements, 4054 (34%) complied at the start of follow-up up to eight cumulated months, 1113 (9%) complied at least once during later follow-up up to eight cumulated months, and the remaining 1487 (13%) complied nine or more cumulated months of follow-up.

Conclusion: Although connected BP monitors can collect a high volume of data, the real-life timing of selfmeasurements is far from recommended schedules. We must promote the use of BP monitors as recommended by guidelines and/or learn to analyse more occasional and sparse measurements.

Graphical abstract: <http://links.lww.com/HJH/C563>

Keywords: data mining, digital technology, eHealth, guideline adherence, home blood pressure monitoring

Abbreviations: BP, blood pressure; HBPM, home blood pressure monitoring

INTRODUCTION

S everal home blood pressure (BP) monitors are connected to facilitate self-monitoring or to allow telemonitoring. They can provide reliable and informative data as long as they are validated and used properly. nected to facilitate self-monitoring or to allow teletive data, as long as they are validated and used properly.

Various schedules have been recommended for appropriate home BP monitoring (HBPM), but all of them are guided by the same two principles [1–4]. First, enough measurements must be performed within a given period to accurately represent the patient's average BP. Second, this process must be regularly repeated to detect the onset of hypertension in at-risk patients or to ascertain sustained BP control in hypertensive patients.

Our objective was to analyse the user engagement of individuals who acquired a connected BP monitor. Although this investment indicates the intent to follow-up BP levels, our hypothesis was that various user profiles would emerge from usage data in real-world conditions.

METHODS

This is a multinational retrospective cohort study using data routinely collected with the BPM Connect home BP monitor (Withings, Issy-les-Moulineaux, France). This report complies with the RECORD statement [5].

Connected device

The Withings BPM Connect is an EU class IIa and US Food and Drug Administration (FDA)-cleared connected medical device that performs oscillometric BP measurements. It uses an arm cuff and complies with the International Organization for Standardization Universal Standard for BP monitors (ISO 81060-2:2018) [6,7]. The BPM Connect automatically synchronizes recorded data with a free mobile application (Health Mate) on the user's tablet or

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smartphone, through Wi-Fi or Bluetooth. After sync, BP and heart rate measurements are then stored with date and time in the user's account when their value is inside the validity range of the device $(SBP < 60 \text{ mmHg}$ or $>230 \text{ mmHg}$, $DBP < 40$ mmHg or >130 mmHg).

To create an account on the Withings Health Mate application, users have to enter their age, sex, height and weight. The application also offers training materials: text and video tutorials explaining how to use the device. This training is automatically proposed at the first device usage, available on-demand anytime through the application, as well as in the paper leaflet part of the device packaging. Up to eight users can be associated with the same BPM Connect. After each measurement, the results are self-assigned by the user. When needed, for example, when a relative is testing the device, the data can be assigned to a generic guest user.

Included participants and measurements

We intended to use all available data and, therefore, we did not perform a sample size calculation. We included the data of adult users $(>= 18$ years old) of the BPM Connect who (a) created a personal account to store their measurements, (b) used their BPM Connect for the first time in or after July 2019, (c) performed at least three measurements within the 7 days following the first use of the BPM Connect, (d) had the opportunity to use their device at least 400 days up to the last data extraction on 19 March 2021. Users from all countries were eligible. Only the 400 days after first use were extracted for each user. Guest user accounts were excluded because they can store measurements from multiple users. Accounts with more than 70 measurements per week were excluded because they probably originated from health professionals using the device for their patients. Users with a recorded BMI \leq 15 or $>$ 45 kg/m² were excluded because their arm circumference likely falls outside the validity range of the cuff (22–42 cm).

Data sources, access, and cleaning methods

Withings, the device manufacturer, provided a curated database of BP measurements, each associated with a measurement time, date, and country, as well as an anonymous user id, age, sex, and BMI.

Consistency with home blood pressure measurement timing criteria

International hypertension and HBPM guidelines all recommend performing a sufficient number of BP measurements over a few days to get an accurate and reproducible estimate of the usual average BP. The International Society of Hypertension and the European Society of Hypertension both recommend duplicate morning and evening measurements for 3–7 days before each clinic visit and at least every 3 months [2,3]. The Japanese Society of Hypertension guidelines recommend two measurements in the morning and in the evening for at least 5 days and ideally 7 [4]. The US guidelines recommend at least two readings in the morning and in the evening during the week before a clinic visit, and clinic visits at every 3–6 months [1].

A systematic review of reproducibility studies has confirmed that home BP measurements over 3 days achieve

over 90% of the maximum correlation with ambulatory BP monitoring, largely independent from the timing or number of readings per day (from 2 to 4) [8].

For the main analysis, we defined a timing criterion (criterion M) that was met when at least 12 measurements were performed within three consecutive days. For sensitivity analyses, we used three other criteria (Supplemental table 1, [http://links.lww.com/HJH/C564\)](http://links.lww.com/HJH/C564): two more stringent criteria that required at least four measurements each day during seven consecutive days (criterion S1) or at least four measurements each day during three consecutive days (criterion S2), and one more flexible criterion that required at least 12 measurements within seven consecutive days (criterion F). The use of the BPM Connect was categorized as consistent with a criterion when this criterion was met at least once every 3 months.

Statistical methods

The R statistical software version 3.6.0 was used for data management and analyses [9].

Descriptive statistics

Quantitative data are reported as median (first quartile, third quartile) and categorical variables as count and percentage. Users were categorized as persistent if they performed at least one measurement during the last 90 days of follow-up (between 311 and 400 days after their first use). In nonpersistent users, the duration of persistence was defined as the number of days between their first and their last measurement (< 310 days). A Kaplan–Meier survival curve was used to describe the proportion of persistent users remaining over time.

Time-patterns of blood pressure monitor use in persistent users during the first year of utilization

We considered that the use of the BPM Connect was consistent with criterion M during the 3 months following any sequence of at least 12 BP measurements within three consecutive days (Supplemental Figure 1, [http://links.lww.](http://links.lww.com/HJH/C564) [com/HJH/C564\)](http://links.lww.com/HJH/C564). Consistency with criterion M can evolve over time. The users can change between a consistent and a nonconsistent state along their trajectory from first utilization to the end of follow-up. To simplify the computations, we used monthly rather than daily intervals. A follow-up month was categorized as consistent when its last day was. The trajectory of a persistent user is thus represented as the sequence of 12 consecutive months of follow-up, each one being in one of two possible states (consistent or nonconsistent with criterion M use of the monitor).

We then clustered persistent users according to the similarity between their adherence trajectories using state sequence analysis with an optimal matching edit distance (package TraMineR [10]). State sequence analysis aims to summarize and categorize sequential data (here a sequence of 12 months for each user, each month categorized as consistent or nonconsistent with criterion M) into a limited number of clusters. To categorize the sequences into groups of similar adherence trajectories, we calculated a distance between trajectories. This distance was defined as

the minimal cost of transforming one trajectory into another one using substitutions (changing a month from consistent to nonconsistent) or insertions/deletions (inserting a consistent or nonconsistent month and deleting another one from the sequence, see Supplemental Figure 2, [http://links.](http://links.lww.com/HJH/C564) [lww.com/HJH/C564](http://links.lww.com/HJH/C564)). The more similar the trajectories are, the fewer transformations are needed to go from one to the other, resulting in a smaller distance. This distance was calculated for each pair of trajectories. The trajectories were then clustered using hierarchical clustering based on the calculated distance. The number of clusters was chosen based on the inspection of the hierarchical clustering dendrogram.

For sensitivity analyses, we performed the same procedure as main analysis but with the above prespecified criteria S1, S2, and F (Supplemental Table 1, [http://links.](http://links.lww.com/HJH/C564) [lww.com/HJH/C564](http://links.lww.com/HJH/C564)).

Ethics

Data collection, storage, and processing complied with the European General Data Protection Regulation (GDPR). All users agreed to the anonymous use of their data for research purposes. The research identifiers were strictly anonymous with no existing index table matching them with user identities.

RESULTS

Persistent and nonpersistent users

We included 22 177 adult users of the BPM Connect who used their BPM Connect for the first time after July 2019, and who had the opportunity to use their device at least 400 days up to the last data extraction on March 2021 (Fig. 1). Measurements were performed in 190 different countries. United States, Germany, United Kingdom, and France were the most represented, totalling 80% of users. Among all users, 10 308 (46.5%) did not record

any measurement between 311 and 400 days after their

first use and were considered as nonpersistent (Fig. 2). There was a higher percentage of women in the nonpersistent user group than in the persistent user group (28.9 vs. 22.1%, $P < 0.001$). Other baseline characteristics of persistent and nonpersistent users were similar although differences are statistically significant due to large numbers (Table 1). Median time to the end of use among nonpersistent users was 108 days (IQR 15, 226). During their time of persistence, they used their device as often as persistent users did.

Consistency with self-monitoring timing criterion M among persistent users

The 11 869 (53.5%) persistent users performed 122 day (54, 264) measurements during the first year and were consistent with criterion M 25% (0%, 50%) of this time.

We identified four clusters of trajectories among the 11 869 persistent users (Fig. 3, dendrogram in Supplemental Figure 3,<http://links.lww.com/HJH/C564>). The 5215 users of cluster 1 (44% of persistent users, Fig. 3, cluster 1) typically never performed an appropriate BP measurement sequence during the first year of use. The 4054 users of cluster 2 (34%, Fig. 3, Cluster 2) performed an appropriate BP measurement sequence at the start of the year and possibly thereafter but without totalling more than 8 months of consistent use. The 1113 users of cluster 3 (9%, Fig. 3, cluster 3) did not perform an appropriate BP measurement sequence at the start of the year but they did at a one or more later times during the first year without totalling more than 8 months of consistent use. The 1487 users of cluster 4 (13%, Fig. 3, cluster 4) performed appropriate BP measurement sequences from the start and most of them totalled of consistent use.

Characteristics of users across clusters are reported in Table 2. There was a trend toward older age among users from clusters 1–4. There was no relevant difference between groups regarding sex, BMI, and baseline DBP and SBP, but usage statistics differed across clusters. Users in cluster 1 had a sporadic use of their device throughout the

FIGURE 1 Participants flowchart. ^TTo allow 400 days of follow-up at extraction date (19 March 2021); *arm circumference likely falls outside the validity range of the cuff (22–42 cm); **probably originate from health professionals using the device for their patients.

FIGURE 2 Persistent use over the first year. Kaplan–Meier curve of persistent use of the BPM connect device along the 310 days following first utilization.

first year, with a low number of total measurements. Users from clusters 2 and 3 also had a sporadic use of their device throughout the year, but also bouts of relatively large numbers of measurements over relatively short periods, totalling up to 8 months of consistent use. Their usage statistics are therefore similar. Users from cluster 4 had

repeated bouts of even larger numbers of measurements over short periods, ensuring sustained consistency over the first year with a large total number of measurements. Users of cluster 4 had in median 43 (28–68) measurement per month, but only 7 (0.5%) had daily measurements and 174 (11.7%) had weekly measurements.

Quantitative data are reported as median (first quartile; third quartile) and categorical variables as count (percentage). BP, blood pressure; UK, United Kingdom; USA, United States of America. a Corresponds to 145 different countries.

FIGURE 3 Plots of self-measurement trajectories according to their consistency to the main criterion. Representation of individual trajectories, that is, states sequence of periods consistent with criterion M (blue) or nonconsistent with criterion M (grey) for each user, in the four identified clusters.

Sensitivity analyses (criteria S1, S2, and F)

All sensitivity analyses identified the four same type of clusters but with different number of users in each cluster (Supplemental Figures 4–6,<http://links.lww.com/HJH/C564>). The more stringent the criterion was, the higher number of users in the group with almost no time spent consistent with it was: 3655 (31%) for criterion F, 8145 (69%) for criterion S2, and 10 931 (92%) for criterion S1.

Quantitative data are reported as median (first quartile; third quartile) and categorical variables as count (percentage). BP, blood pressure; UK, United Kingdom; USA, United States of America.
ªCorresponds to 145 differen

In the whole population, users spent 71% (41–100%) of the time with at least 12 measurements over the last 3 months, but these measurements were often too scattered to be consistent with criteria S1, S2, M, or F. The percentage of time spent consistent with criteria over a year was respectively 0% $(0-0\%)$ for criterion S1, 0% $(0-25\%)$ for criterion S2, 25% (0–50%) for criterion M, and 39% (17– 72%) for criterion F. When looking at the different clusters identified using main analysis, users of cluster 1 ($n = 5215$, 44% of users) had almost no time spend consistent with any of the four criteria (Supplemental Table 2, [http://links.lww.](http://links.lww.com/HJH/C564) [com/HJH/C564](http://links.lww.com/HJH/C564)). Even in the cluster with the highest number of measurement (cluster 4, $n = 1487$, 13% of all users), users had only 0% (0–27%) of time spent consistent with criterion S1 and 51% (26–74%) with criterion S2, while they spent 90% (79–100%) of the time consistent with criterion M, and 100% (89–100%) with criterion F.

DISCUSSION

Key results

Our study pictures the real-world engagement of users who bought a connected BP monitor. It shows that about half of them continued to perform measurements over the first year but only a fifth of these consistently performed sequences of repeated measurements. The proportion of users and the percentage of time consistent with a BP measurement timing criterion is sensitive to definition changes.

Interpretation

Only 53.5% of users persistently used their device after 1 year. Another study on home BP monitoring with wireless devices reported that 79,2% of users had taken no measurements during week 52 [11]. Although 66.2% used the same device (Withings) as in our study, we do not know if they had no measurement during the last 3 months of followup either.

Among persistent users, we identified four patterns of engagement with home BP monitoring based on consistency with a BP measurement timing criterion. The largest group of users (44%) had no time spent consistent with the measurement timing criterion, whereas 13% of users performed measurements consistent with the timing criterion most of their follow-up time. Participants in the group with the highest engagement were about 5 years older than those in the group with the lowest engagement. Older age was also reported as an independent factor of better adherence to home BP monitoring in previous studies [11– 13]. Although statistically significant, the differences in baseline BP across groups are very small and therefore cannot be considered a major factor in explaining subsequent user engagement differences.

Finally, other BP measurement timing criteria were associated with dramatically different proportions of time spent consistent with them. In the group with the highest number of measurements, users spent a median of 0% of the time consistent with the more demanding criterion, which required at least four measures each day during seven consecutive days, at least every 90 days, a criterion very close from numerous guidelines [1–4]. In the same group, users spent a median of 100% of the time consistent with the

more flexible criterion, which required at least 12 measurements over a period of 7 days.

Strength and limitations

With follow-up data from over 20 000 individuals during 1 year, our study belongs to the largest ones reporting realworld HBPM measurements [14–17]. Large longitudinal data require adequate statistical methods to summarize trends over time, like here the consistency with BP selfmeasurement timing criteria. We represented the sequence of individual BP measurements over time as trajectories. Unlike rough descriptive data as the mean number of BP measurement or the mean time spent consistent with a predefined schedule, trajectory analysis accounts for the inter-individual and intra-individual variability of measurements over time. It also allows the classification of individuals into subgroups with similar patterns of use, and identifies several typical trajectories rather than a single average trajectory [18,19].

Nonetheless, our study suffers from limitations. First, our main criterion for appropriate use demands at least 12 BP measurements over 3 consecutive days. It is a simplification of recommendations, which require often at least two consecutive morning measurements and two consecutive evening measurements over 3–7 days. Results from main analysis therefore overestimate the consistency to most recommended measurement timings. We thus performed sensitivity analyses with more stringent and more flexible criteria to give a more diverse appreciation of BP selfmeasurement behaviours. Second, the sample is only representative of buyers of a connected home BP monitor, indicating some degree of health concern and technological awareness. Many individuals, including hypertensive patients, do not monitor their BP at home or prefer simple unconnected monitors to do so [20]. Third, we have no information on the motives and goals of users. We do not know whether HBPM was recommended by a healthcare professional and if so, whether a measurement protocol was also recommended. Alternatively, users may have purchased the device on their own initiative and if so, with different goals: hypertension self-management, wellness documentation, curiosity... We also lack clinical information on users, including whether they were hypertensive or not, whether they took BP-lowering medications or not, and whether that changed during follow-up. This precludes analyses of BP level evolution over time.

Generalizability

Our results represent the engagement of spontaneous users of a connected BP measurement device. Whether they extend to the whole target population of patients eligible to HBPM, who may be less tech-proficient but more healthconcerned, is uncertain.

HBPM measurement performed by patients in more formal settings, with instructions and feedback by healthcare professionals, are likely to be more appropriate.

In the context of randomized controlled trials with hypertensive patients, intensive training [21] or less intensive training coupled with daily reminders [22] achieved as high as 90% adherence to the recommended schedule within the first 2 weeks of use and 70–80% persistence

of use at 12 months. Adherence to prescribed schedules is also around 80% in hypertensive women throughout pregnancy, probably because of the high stakes of BP monitoring in this circumstance [23,24].

Perspectives

Connected devices are now part of our daily life and they easily provide a large amount of data. The next challenges are to ensure they are used appropriately for the data to be accurate and informative, and to define methodological standards for the analysis of collected data. Cuffless devices have the potential to provide even more longitudinal data, but their performance and validity are currently uncertain [25]. Certain devices require regular calibration, which demands additional caution to maintain accuracy and reliability of data. As cuffless technology evolves, continuous evaluation and rigorous validation will be crucial to establish their effectiveness in clinical and research settings.

Clinical perspectives

Connected HBPM has obvious advantages related to the automated transmission of data: it is less cumbersome and less error-prone than copying, it can be easily coupled with subsequent data processing such as appropriateness checks (timing and number of measurements) or calculation of average BP levels [16,26–28]. However, adherence to good HBPM measurement practices must be ensured for the results to be usable in clinical practice.

The instruction manual of the connected BP device currently does not suggest any measurement schedule, because more than one are appropriate. Promoting one of them specifically could conflict with equally appropriate instruction provided by the patient care provider or national guidelines. However, the principles of appropriate use (repeated measurements at predefined times of the day, over several days) could be explained in the manual, as well as the most frequent errors (too few measurements, single measurements performed sporadically...).

Health professionals promoting the use of HBPM, with connected or unconnected devices, must acknowledge the need to instruct and train patients before they use a BP monitor. They must also take the opportunity to quickly check how BP measurements were performed and provide feedback every time they discuss the results of BP selfmeasurements.

Mobile applications can also be coupled with connected home BP monitor and guide users through appropriate measurement schedules. These applications are well received by users and may improve their adherence [24,29]. One of them, the HERB system, including a connected home BP monitor, a mobile educational program and a web application for supervision by healthcare providers, allowed a better BP control than standard practice during a Japanese randomized controlled trial [30].

Research perspectives

Further research is needed to investigate how best to promote large-scale adoption of good measurement practices for home BP. Even with the perfect mix of baseline training, reminders, and feed-back, long-term adherence to

a fixed measurement schedule is difficult. From a practical point of view, obtaining an adequate number of measurements for accurate average BP calculation over a given period is more likely to succeed if the patient can flexibly fit the schedule. A qualitative study showed that patients not only appreciate the guidance provided by structured schedules but also value the possibility to accommodate the measurement to their individual circumstances and charges [31]. Constraining users is unlikely to provide large benefits. For example, precluding automated BP monitors to perform more than a fixed number of measurements at predefined times increased the 7-day adherence with a prescribed schedule from 23 to 40%, far from what is achieved by training and follow-up [32].

Further research is also needed to discern when home BP measurements can be legitimately used although they do not perfectly fit recommended schedules, and how best to analyse and interpret them in these cases. A preliminary study suggests that even if the patient does not comply with the prescribed schedule, five to seven random BP measurements over a week provide a reproducible average [33]. When hypertensive patients were asked to self-monitor their BP at least six times per week using a connected device, with a monthly follow-up by phone, 73% were able to comply over 6 months [12].

To conclude, our study highlights the strengths and limitations of real-world BP measurements collected through a connected device for clinical and research purposes. In principle, a high volume of data can be easily collected. However, half of users stop performing measurements within the first year after purchase. Among those who continue, less than 25% comply with a permissive measurement timing criterion over the whole year of follow up. To widen the scope of potential uses of home BP measurements for clinical and research purposes, we must promote the use of BP monitors as recommended by guidelines but also learn to analyse more flexible datasets that do not perfectly meet these recommendations.

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Accessibility of protocol, raw data, and programming code: request regarding data should be made by contacting health@withings.com. The statistical code is available upon request to the corresponding author of the study.

Conflicts of interest

V.V. and P.D.V. report perceiving a salary as permanent employees of Withings (not specifically for the present manuscript). The other authors report no financial interests or potential conflicts of interest.

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