Η χρήση των φορητών συσκευών και εφαρμογών για την εκτίμηση καρδιομεταβολικής υπέρτασης ασθενών

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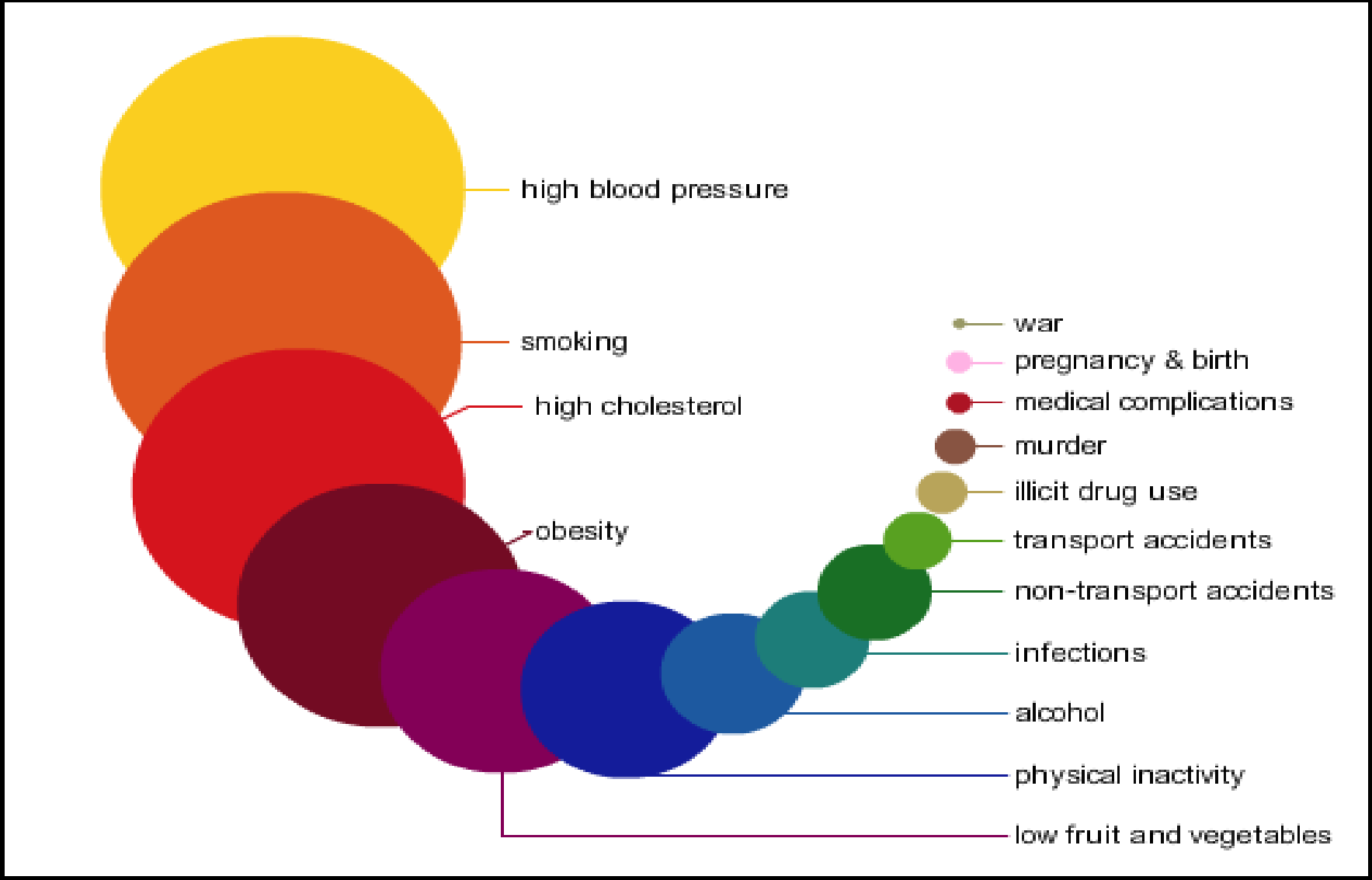
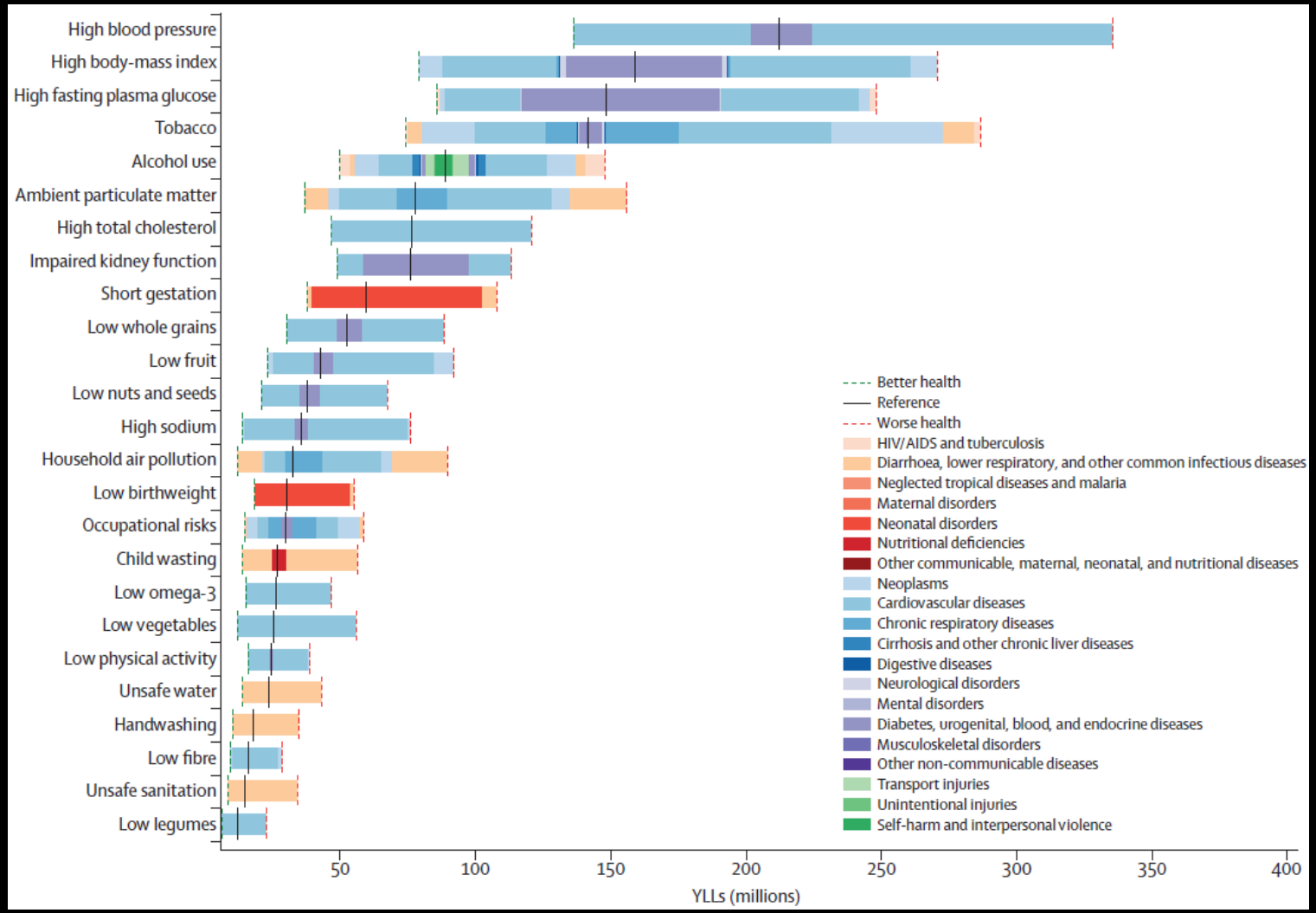
ΓΝΑ Ιπποκράτειο

- Conflict of interest: MEDTRONIC, SERVIER, WINMEDICA, ASTRA ZENECA, ELPEN, SANOFI, MENARINI, IASPIS, UNI-PHARMA, NOVO NORDISK, VIANEX, KRKA, IASIS PHARMA, MERCK

Risks leading to death



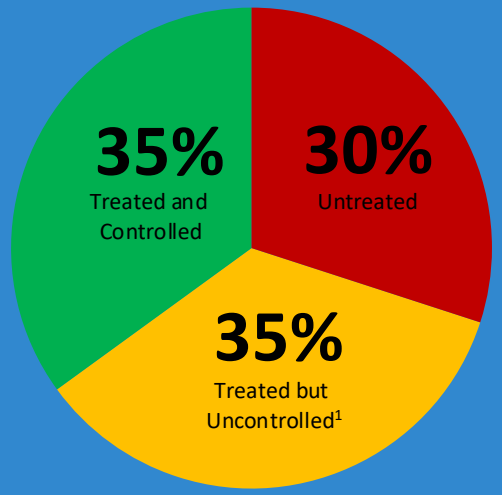
Leading 20 risk factors contributing to the global risk-attributable YLLs in 2040



Foreman KJ, et al. Lancet. 2018 Nov 10;392(10159):2052-2090

The unmet need in managing hypertension

HTN is estimated to have **added $18.6B in avoidable costs*** to the US health care system alone



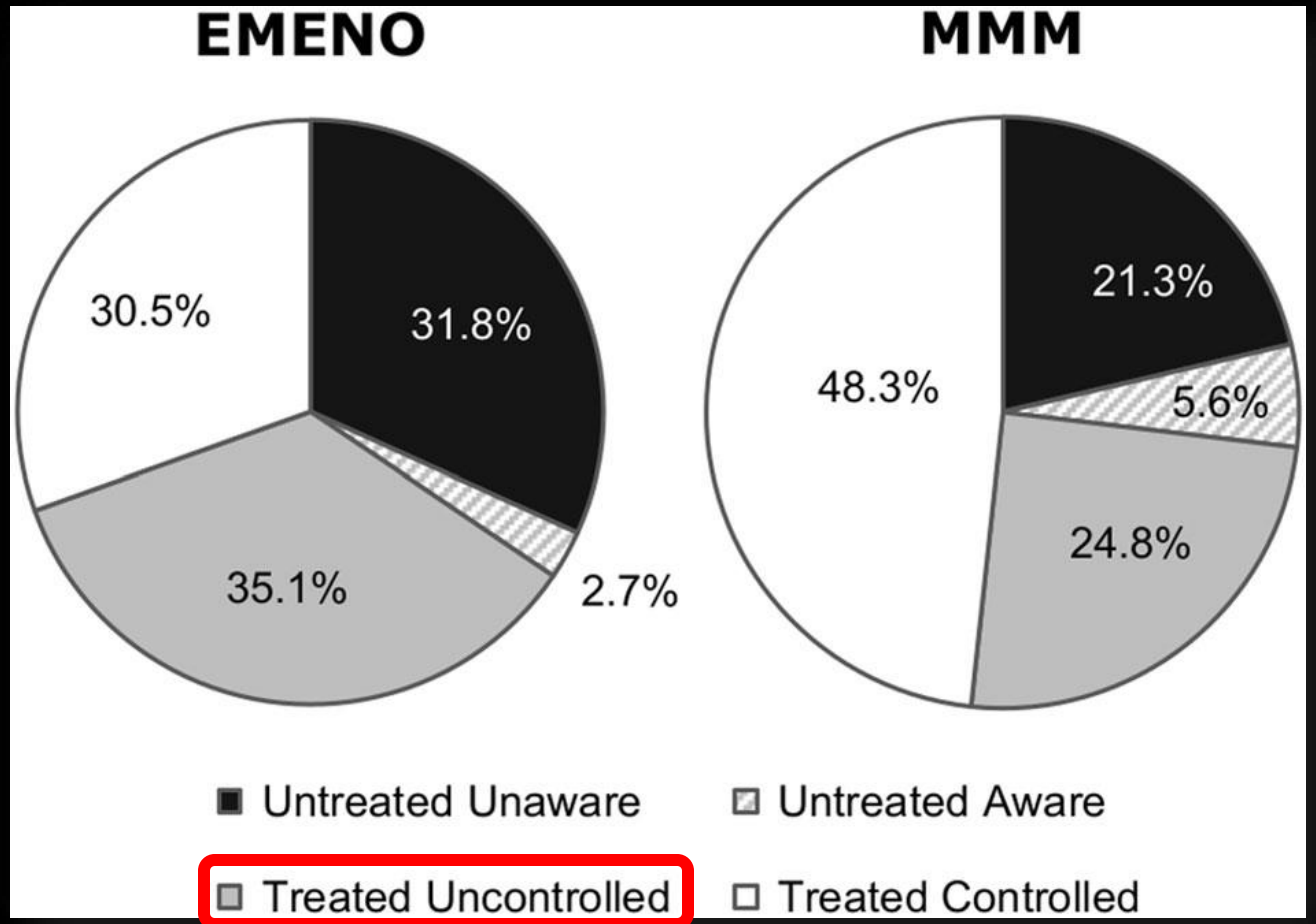
1 IN **3** ADULTS HAVE HTN

1B PEOPLE WORLDWIDE

1.6B BY 2025

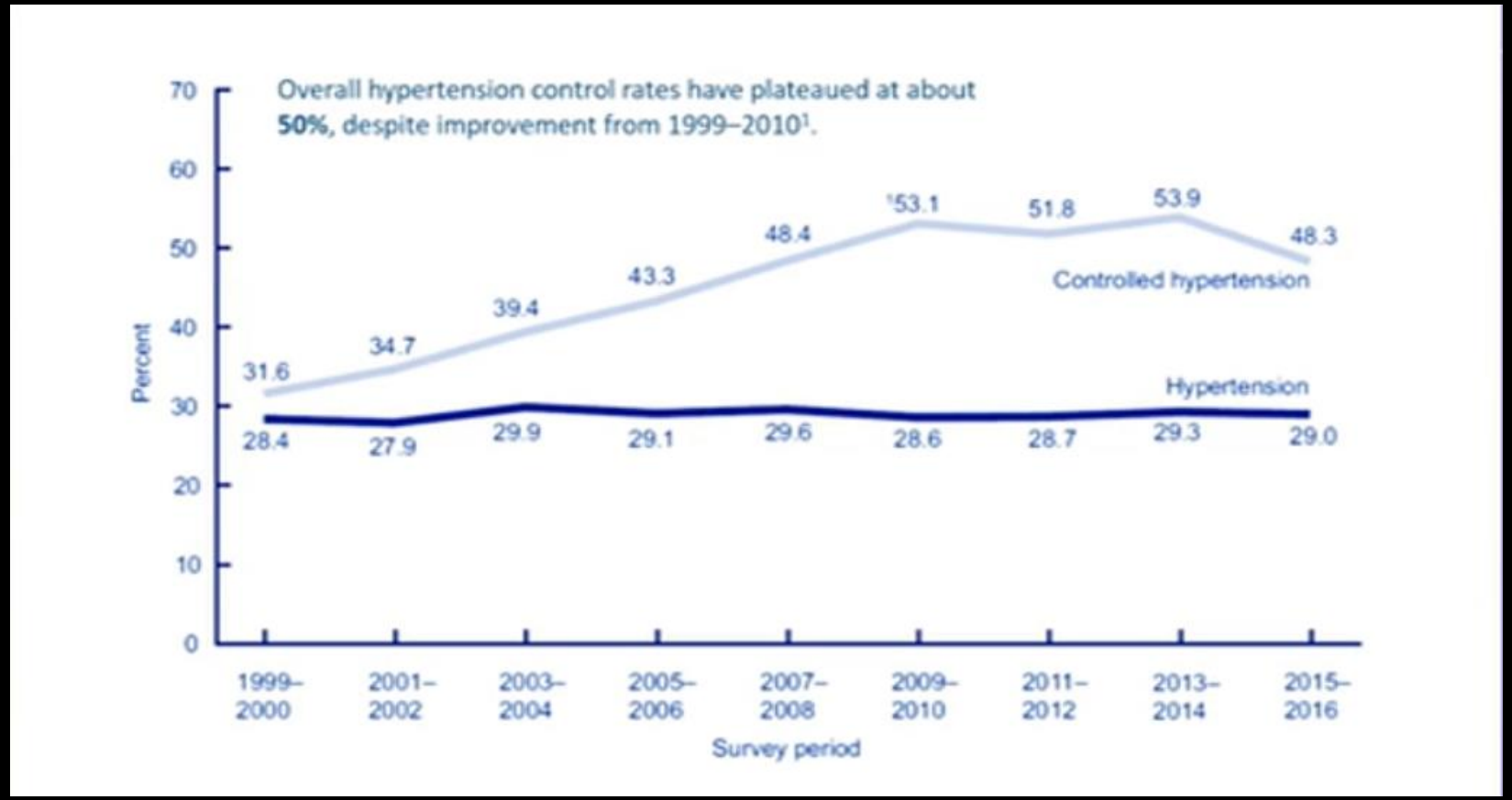
Kearney PM, et al. Lancet. 2005 Jan 15-21;365(9455):217-23
Messerli FH et al. The Lancet. 2007;370:591–603
WHO Report 2002: Reducing risks, promoting healthy life

Awareness, treatment and control of hypertension in EMENO and MMM studies



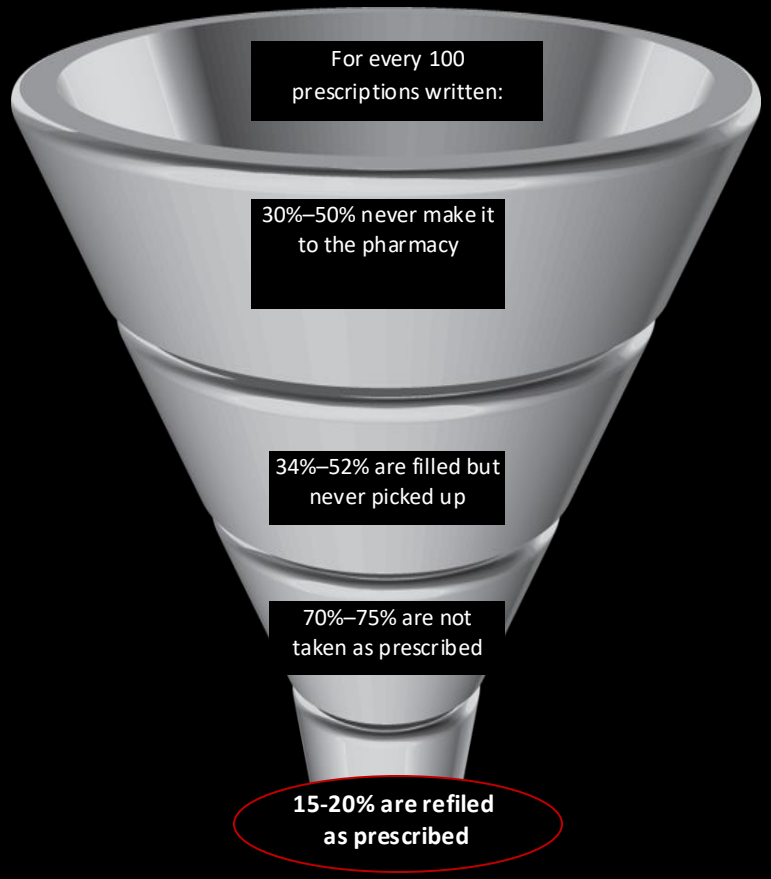
Menti A, et al; J Hum Hypertens. 2021 Apr 9. Epub ahead of print
Stergiou GS, et al; Eur Heart J Suppl. 2021 May 20;23

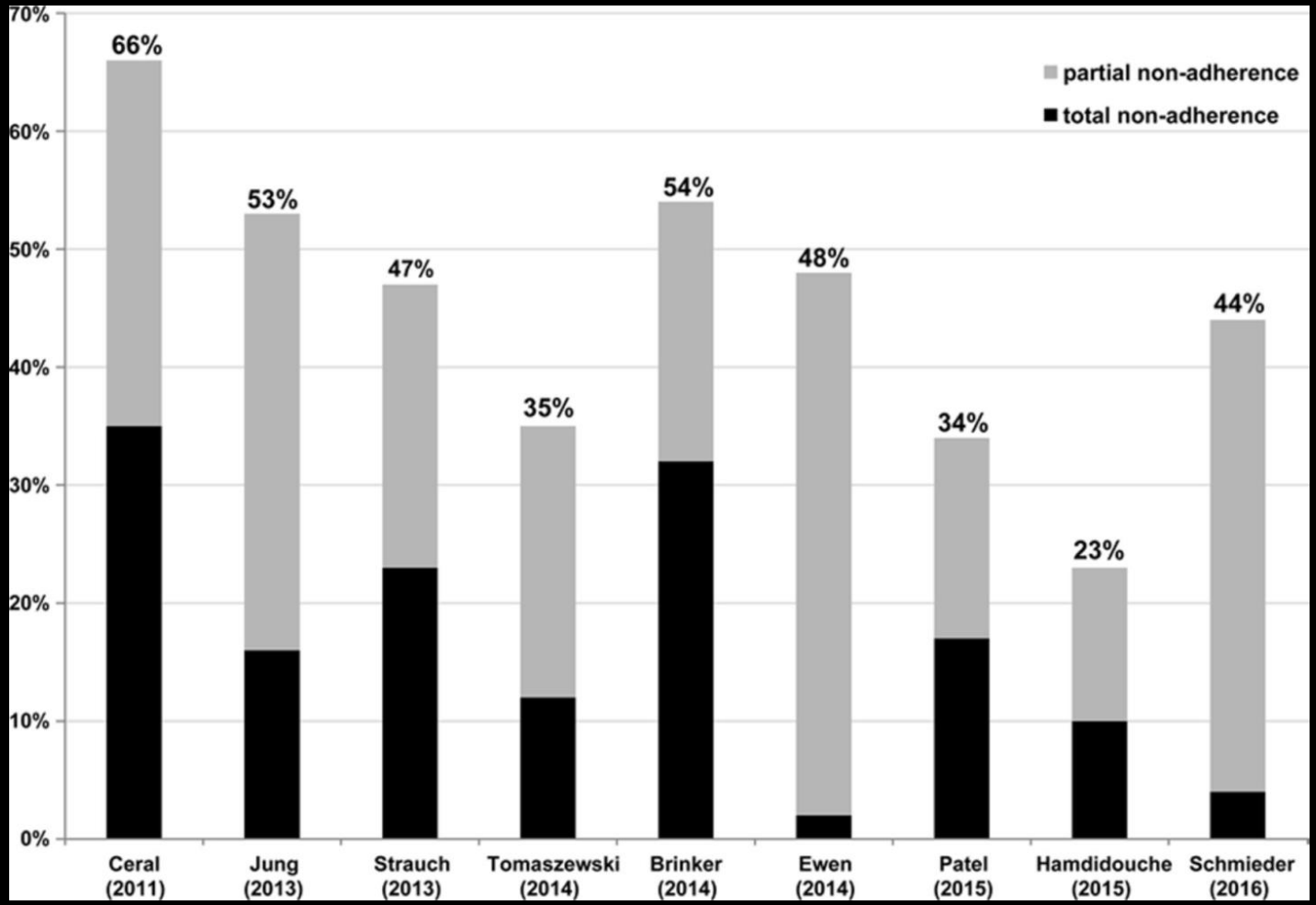
Current strategy is failing to improve HTN control



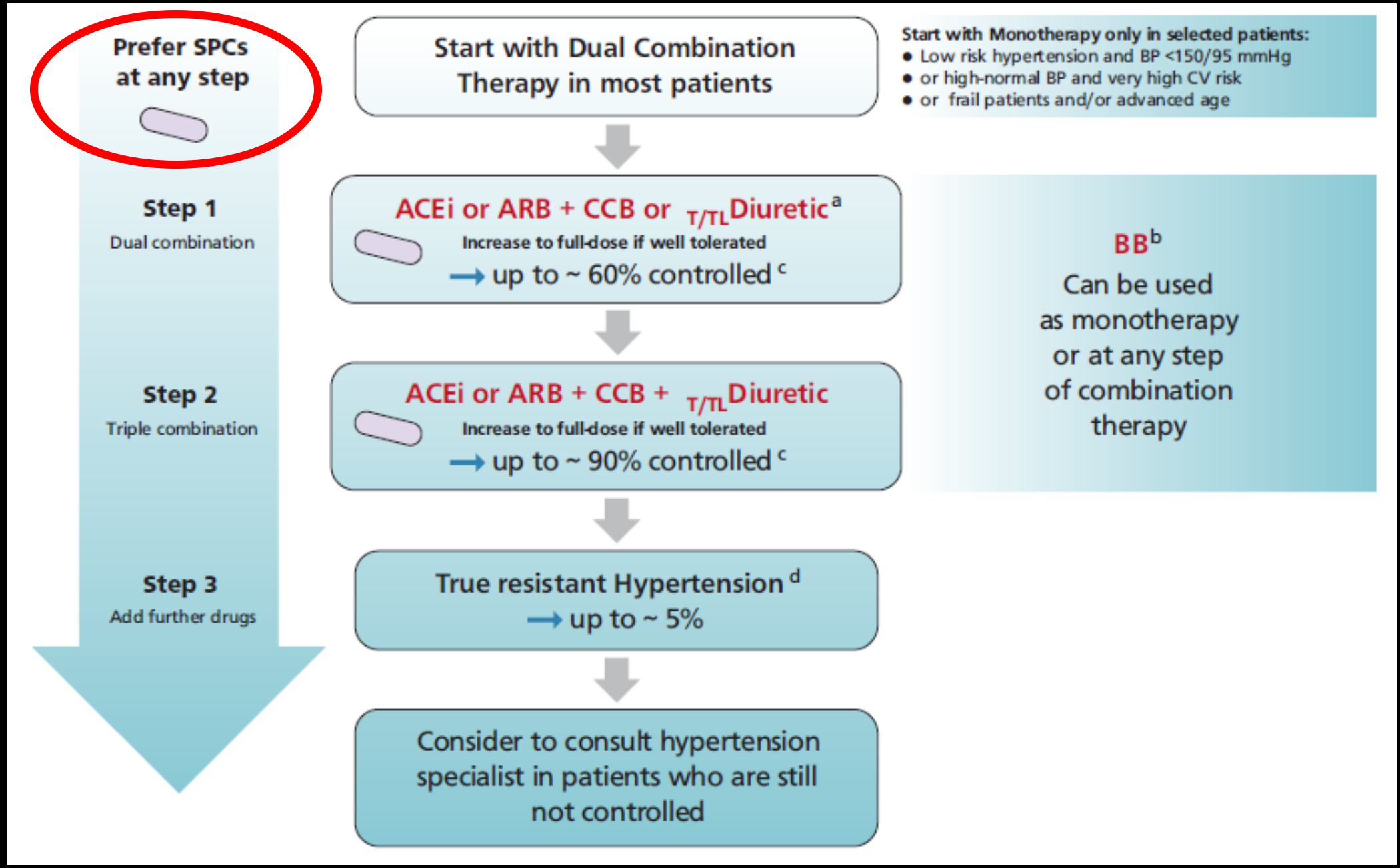
Fraya et al. NCHS Data Brief. 2017; 289: 1-8

Adherence





Berra E, et al. Hypertension. 2016 Aug;68(2):297-306

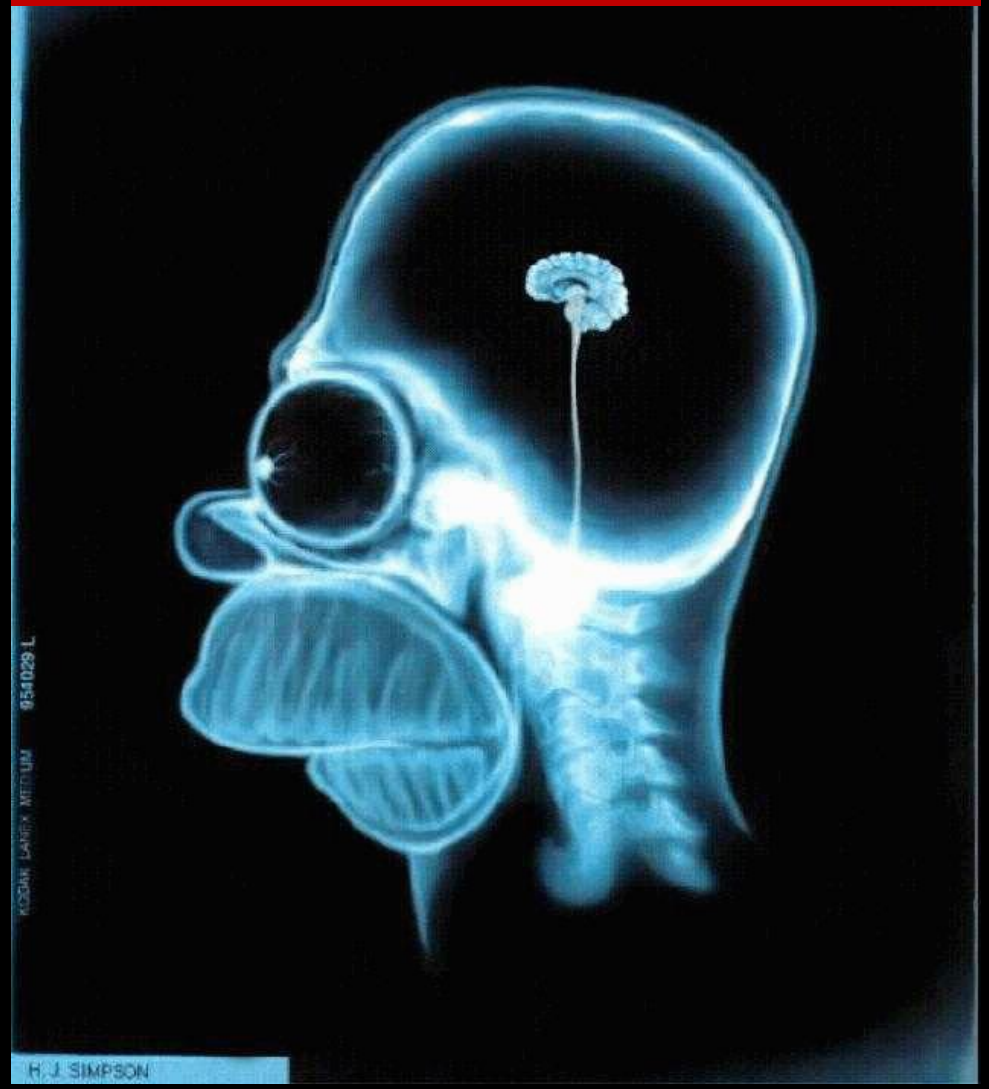

Prefer SPCs at any step
Start with Dual Combination Therapy in most patients
Start with Monotherapy only in selected patients:
• Low risk hypertension and BP <150/95 mmHg
• or high-normal BP and very high CV risk
• or frail patients and/or advanced age
Step 1
Dual combination
ACEi or ARB + CCB or T/TL Diuretic[a]
Increase to full-dose if well tolerated
→ up to ~ 60% controlled[c]
Step 2
Triple combination
ACEi or ARB + CCB + T/TL Diuretic
Increase to full-dose if well tolerated
→ up to ~ 90% controlled[c]
BB[b]
Can be used as monotherapy or at any step of combination therapy
Step 3
Add further drugs
True resistant Hypertension[d]
→ up to ~ 5%
Consider to consult hypertension specialist in patients who are still not controlled

ESH 2023

“The Good Doctor”

1. Diagnosis
2. Treatment
3. Implementation

“Medicine is an art based on science”



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops

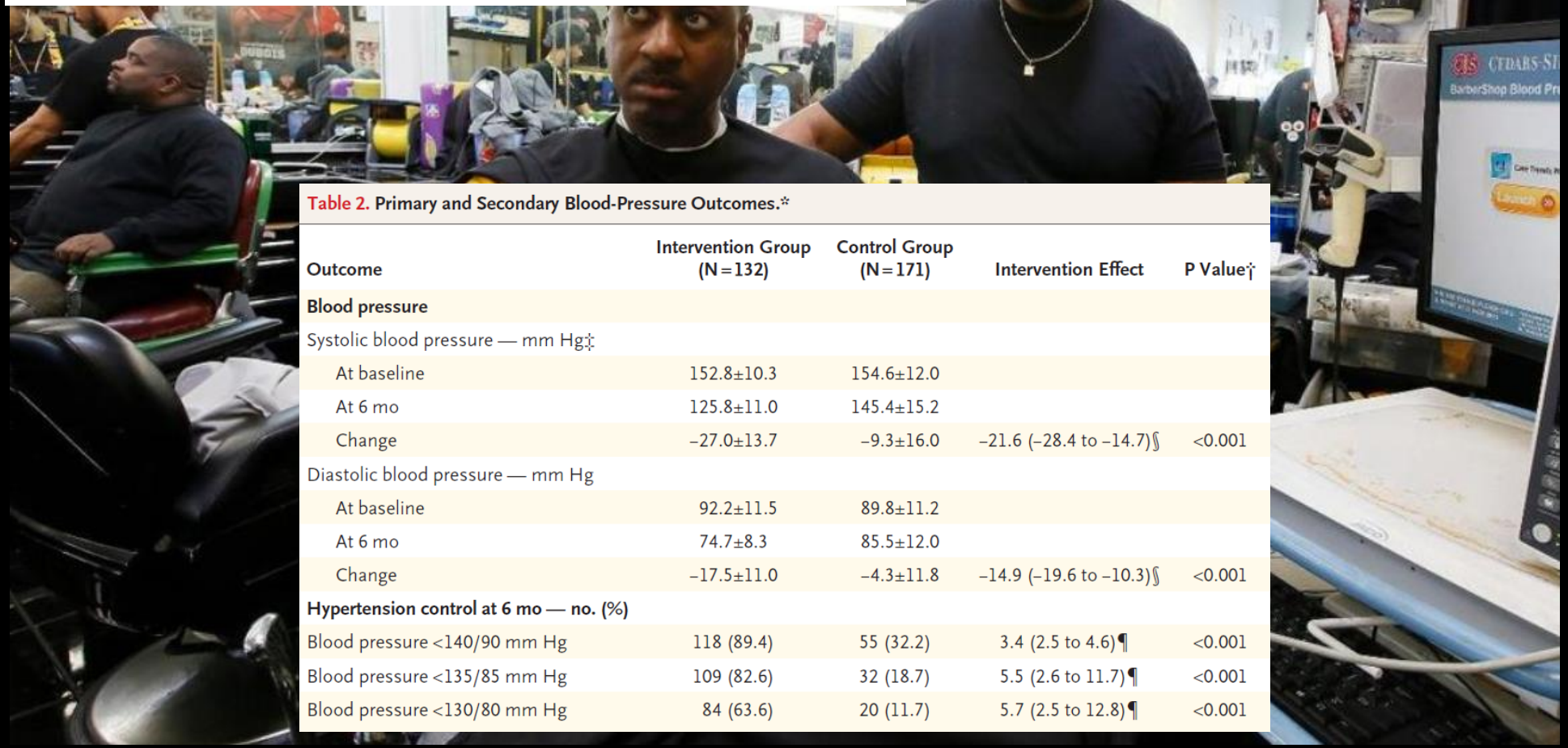
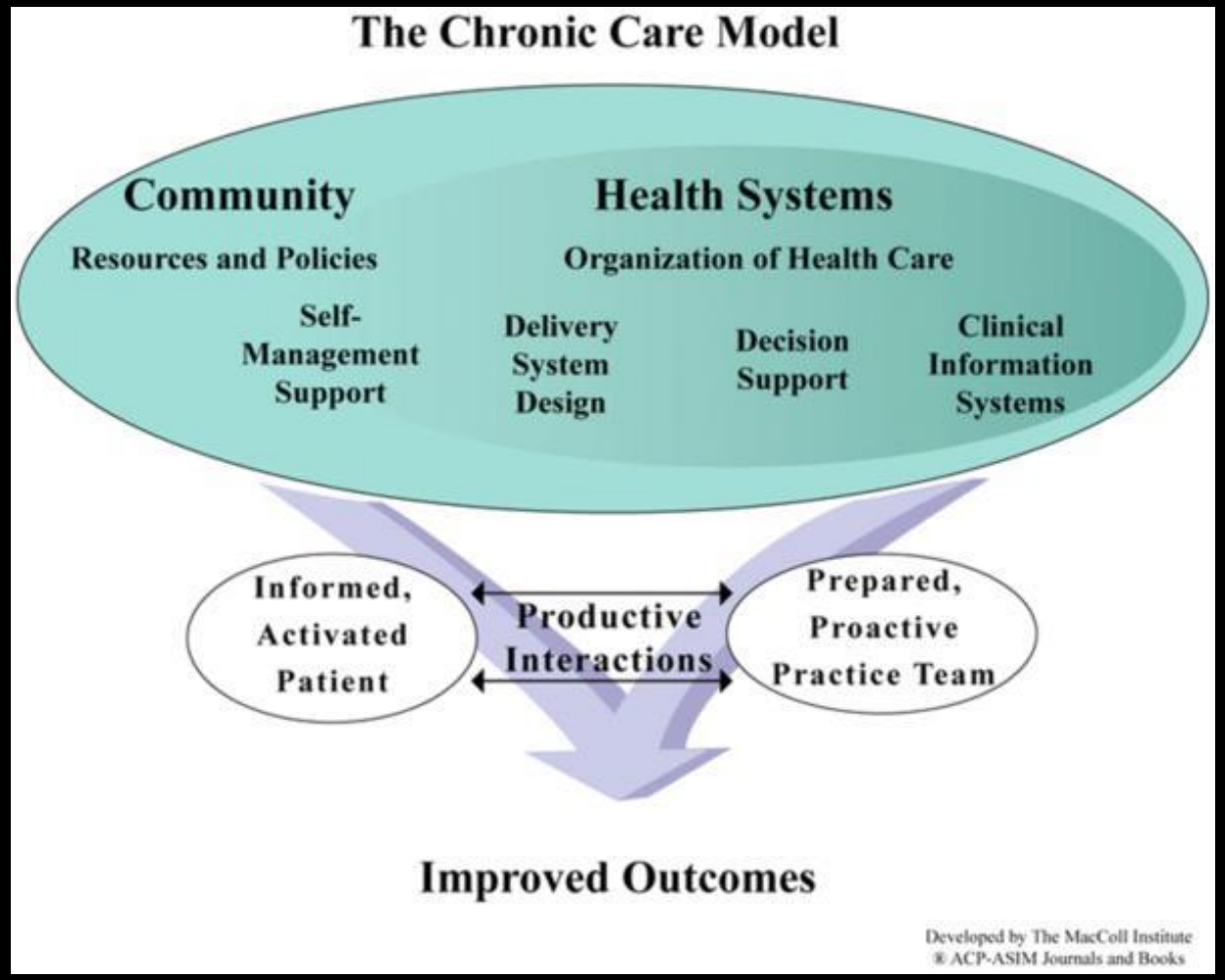


Table 2. Primary and Secondary Blood-Pressure Outcomes.*

Outcome	Intervention Group (N=132)	Control Group (N=171)	Intervention Effect	P Value†
Blood pressure				
Systolic blood pressure — mm Hg‡				
At baseline	152.8±10.3	154.6±12.0		
At 6 mo	125.8±11.0	145.4±15.2		
Change	−27.0±13.7	−9.3±16.0	−21.6 (−28.4 to −14.7)§	<0.001
Diastolic blood pressure — mm Hg				
At baseline	92.2±11.5	89.8±11.2		
At 6 mo	74.7±8.3	85.5±12.0		
Change	−17.5±11.0	−4.3±11.8	−14.9 (−19.6 to −10.3)§	<0.001
Hypertension control at 6 mo — no. (%)				
Blood pressure <140/90 mm Hg	118 (89.4)	55 (32.2)	3.4 (2.5 to 4.6)¶	<0.001
Blood pressure <135/85 mm Hg	109 (82.6)	32 (18.7)	5.5 (2.6 to 11.7)¶	<0.001
Blood pressure <130/80 mm Hg	84 (63.6)	20 (11.7)	5.7 (2.5 to 12.8)¶	<0.001

Victor RG, et al. N Engl J Med. 2018 Apr 5;378(14):1291-1301

The Modern Model of chronic disease management



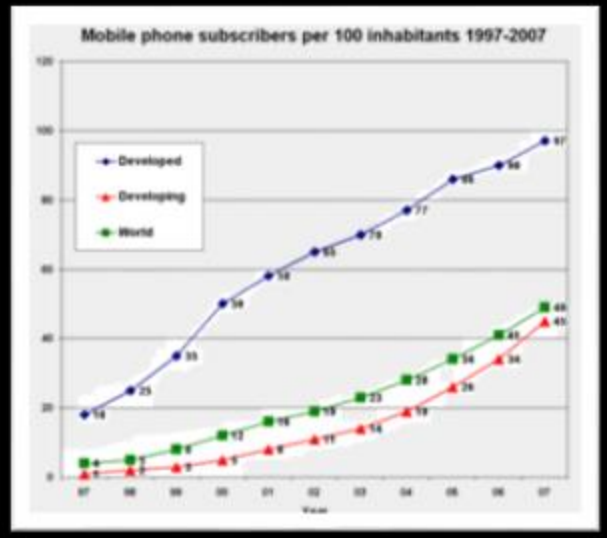
According to a modern model of HTN management, **the patient and not his/her disease has a central role** and is **directly involved in his/her health care management** in collaboration with the physician, family, and community, each other interacting in different ways to influence and support health decision.

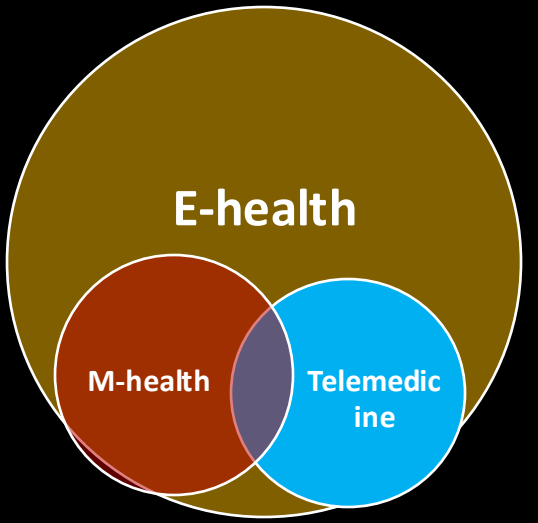
An individualized or personalized approach is required, according to a modern medical model often referred to as "precision medicine".

Carter BL, et al. J Clin Hypertens 2012 14:51–65
Melville S, Byrd JB. Curr Hypertens Rep 2019 21:13

The revolution

- The explosive growth of the Internet economy and the reform of medical treatment systems have accelerated the growing mHealth market.
- At present, the mHealth APP market is explosively growing due to the popularization of smartphones

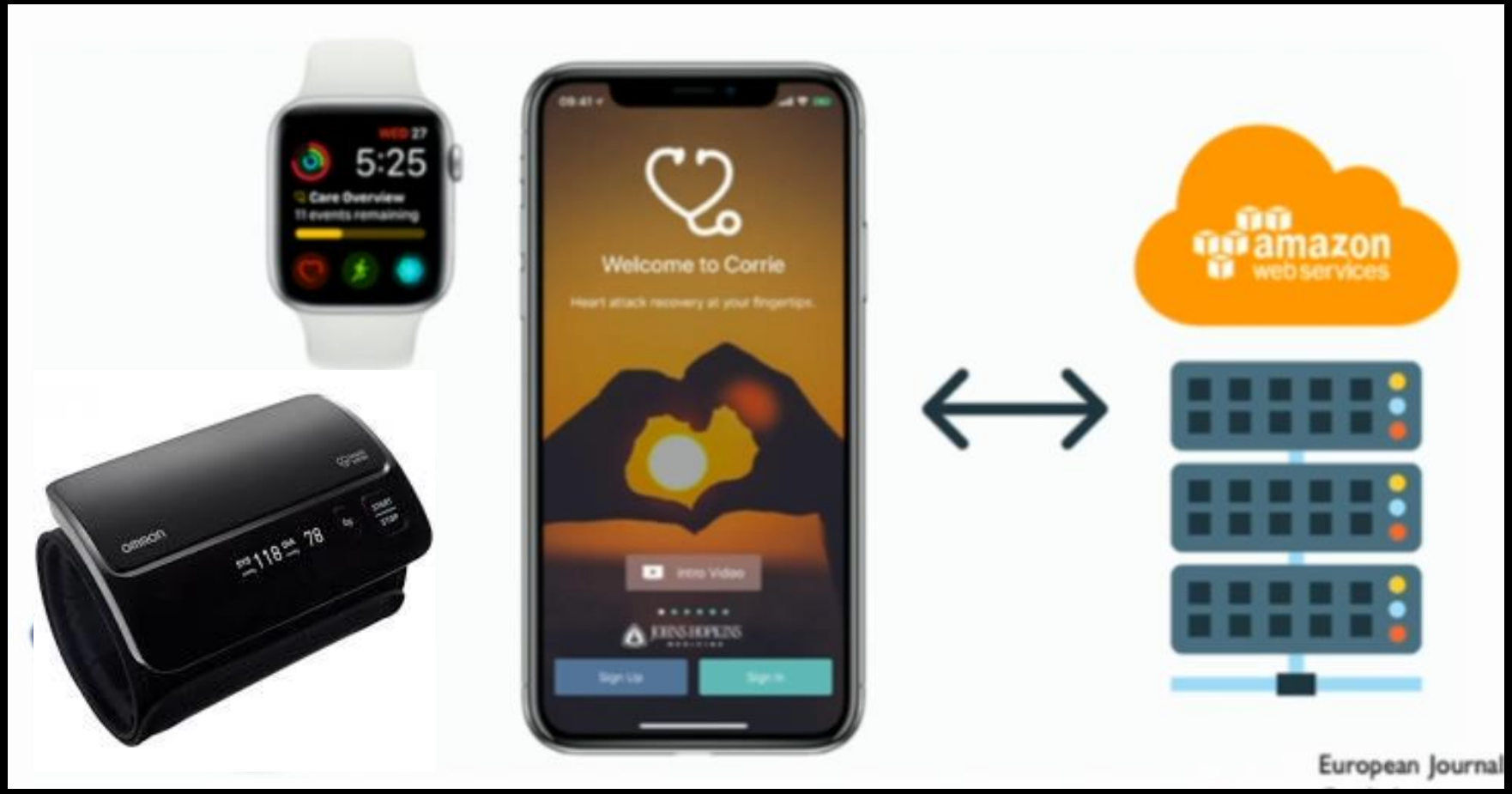




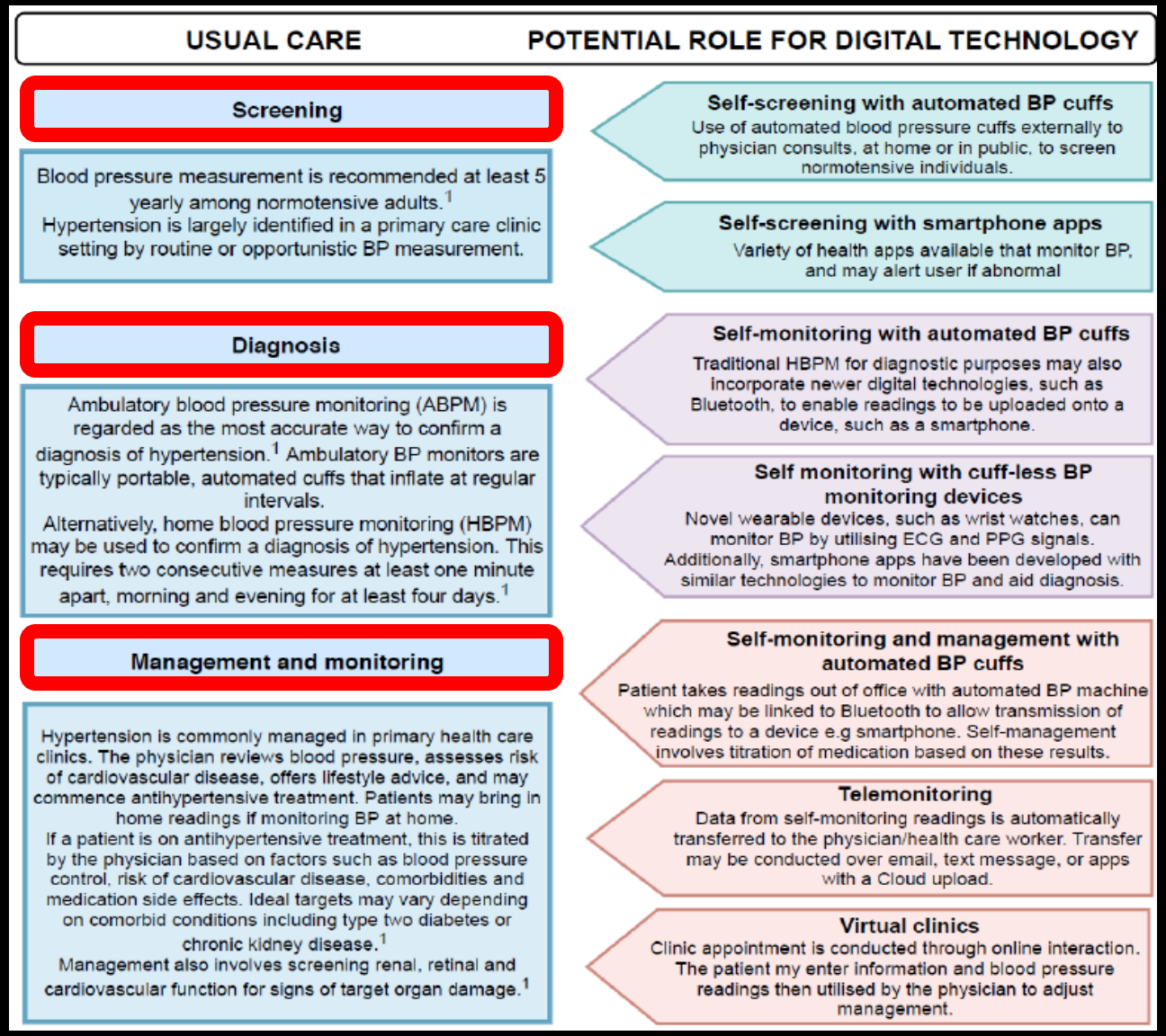
The smartphone revolution is under-hyped, more people have access to phones than access to running water. We've never had anything like this before since the beginning of the planet.

(Marc Andreessen)

Transition from “all medicalized devices” to medical sensors adapted to usual used app and systems

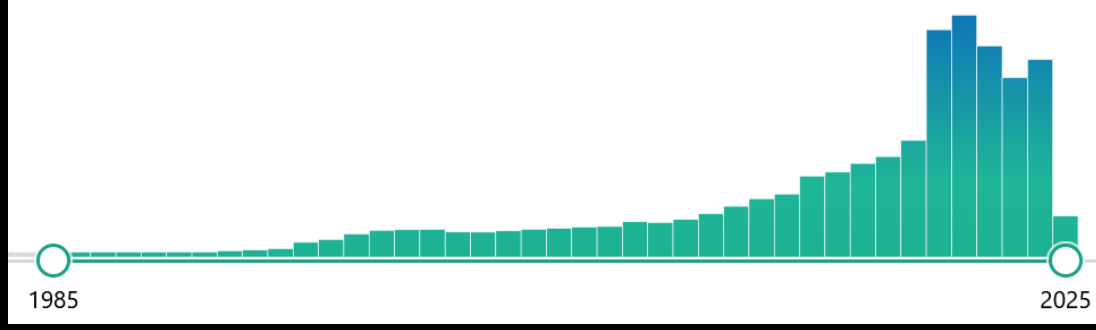


How digital technology may fit into future models of care

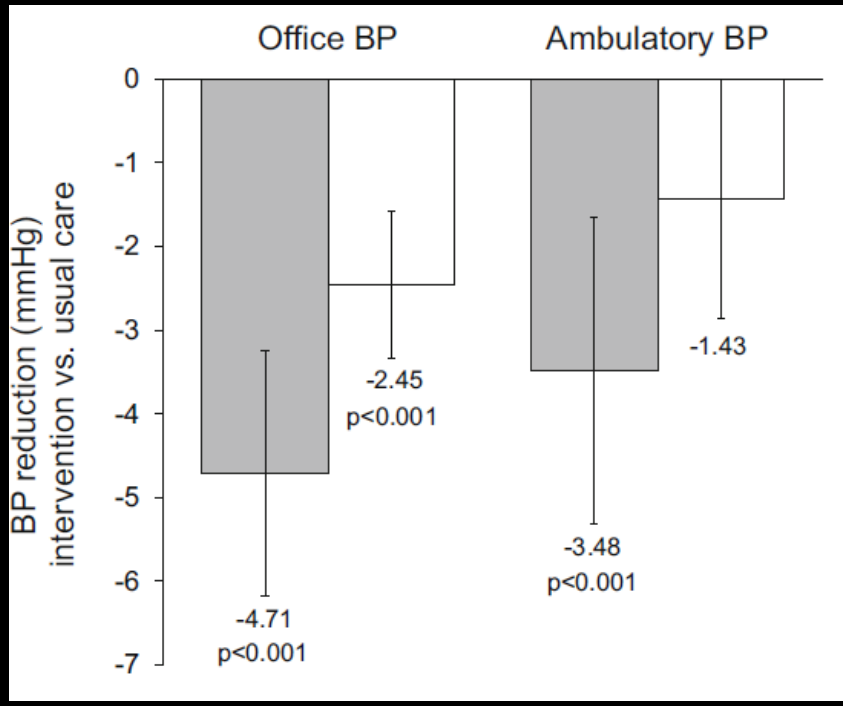


Kitt J, et al. J Cardiol and Cardiovasc Sciences. 2020;4(1):18-23

Telemedicine



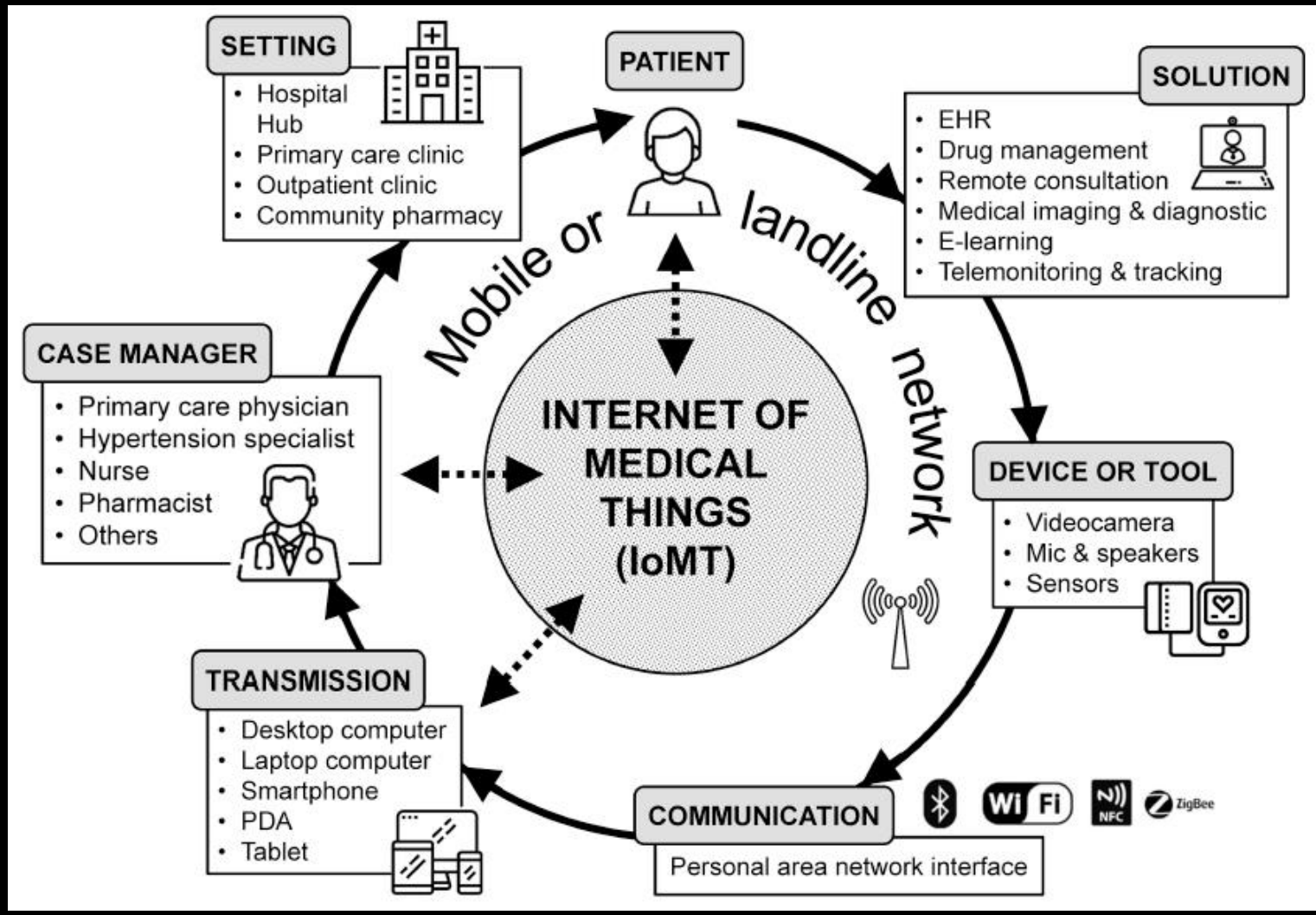
- Can reinforce and empower the physician-patient relationship, may even try to individualize it
- Patients to easily and rapidly communicate to their doctors the occurrence of acute symptoms or sudden BP raises
- Can reduce patients' stress
- May help empowering hypertensive patients, influencing their attitudes and behaviors, and improving their medical condition
- Physicians can provide services to an increased number of patients



Omboni S, et al. High Blood Press Cardiovasc Prev. 2016 Sep;23(3):187-96

Telehealth Services

- **7 million patients** are managed by telehealth solutions around the world
- In **US** there are **200 telemedicine networks** with 3,500 service sites and over half of all US hospitals have adopted some form of e- health
- In **Europe**, **83% of countries have telemedicine services** implemented, the main being teleconsultation (73%), followed by telediagnosis and telemonitoring (67%)
- m-health apps can provide automatic patient-directed feedbacks or overcoming of preset thresholds and have the function of positive reinforcement of doctor's prescription and recommendation

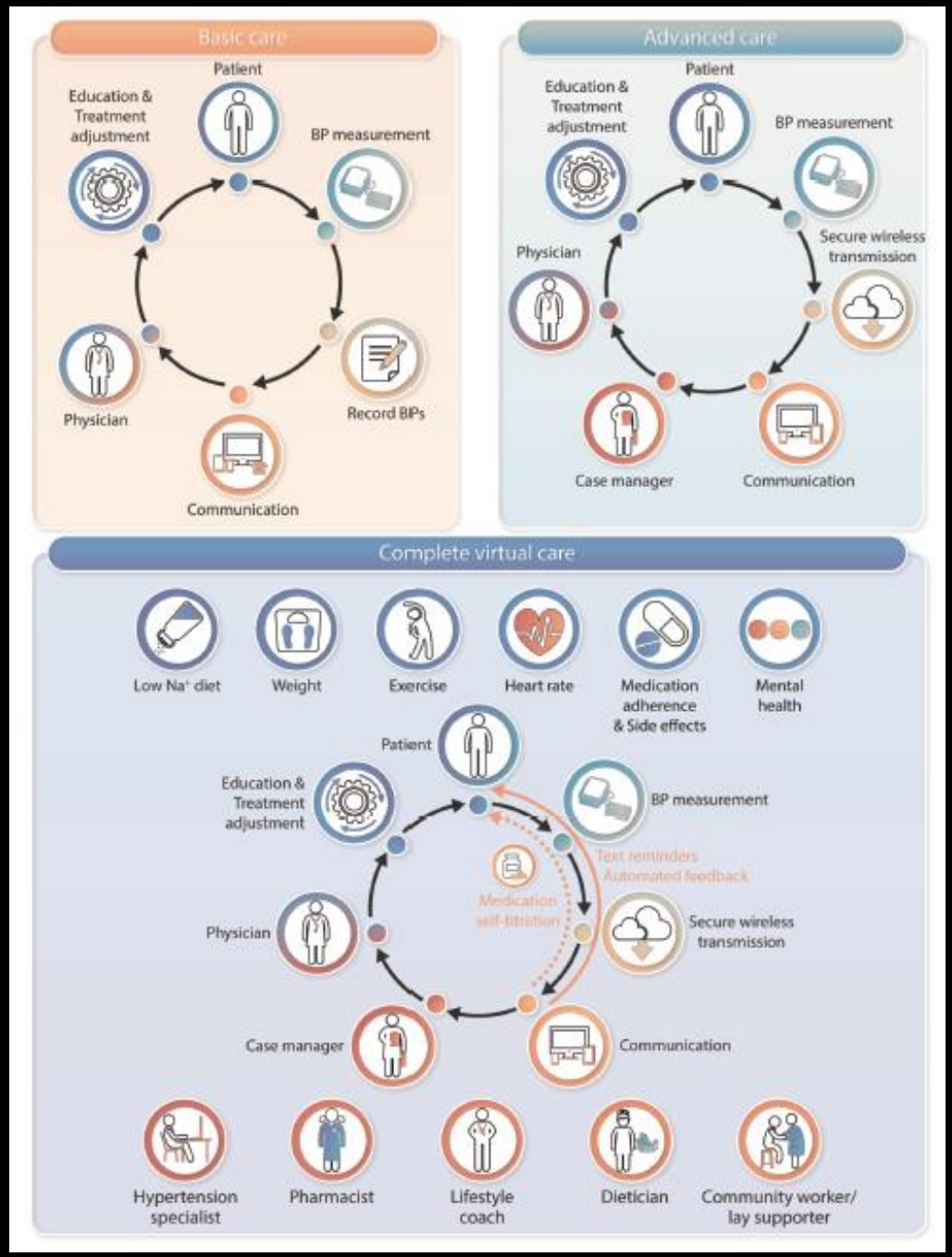


Omboni S. Front Cardiovasc Med. 2019 Jun 13;6:76

Consensus Document

Virtual management of hypertension: lessons from the COVID-19 pandemic: International Society of Hypertension position paper endorsed by the World Hypertension League and European Society of Hypertension

Nadia A. Khan[a], George S. Stergiou[b], Stefano Omboni[c,d], Kazuomi Kario[e], Nicolas Renna[f], Niamh Chapman[g], Richard J. McManus[h], Bryan Williams[i], Gianfranco Parati[j], Aleksandra Konradi[k], Shariful M. Islam[l], Hiroshi Itoh[m], Ching S. Mooi[n], Beverly B. Green[o], Myeong-Chan Cho[p], and Maciej Tomaszewski[q,r]

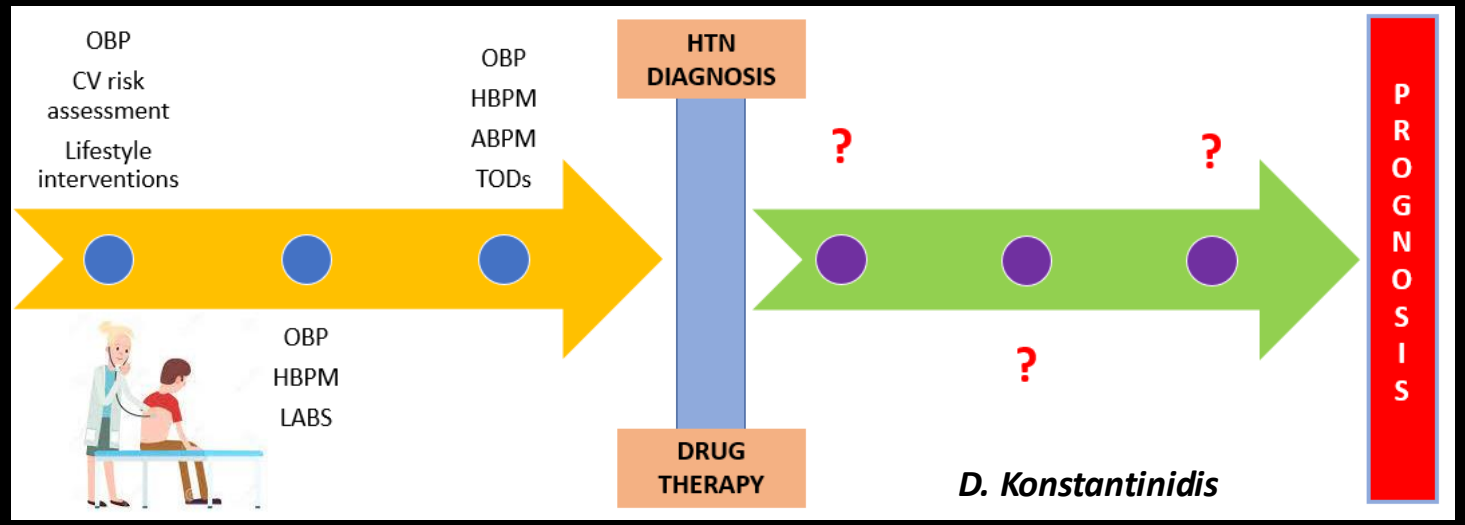


Recommendations

- The initial evaluation should be conducted in person.
- If not possible or preferred, then video based medical consultation is preferred to telephone (see Table 1 resource section for strategies to optimize the virtual healthcare visit)

J Hypertens. 2022 Aug 1;40(8):1435-1448

Diagnosis and management of HTN



✓Appropriate follow-up and monitoring enable assessment of:

1. adverse responses
2. response to therapy
3. adherence
4. target organ damage
5. progress toward treatment goals

ACC/AHA Hypertension Guidelines2017

A Telecommunications System for Monitoring and Counseling Patients With Hypertension

Impact on Medication Adherence and Blood Pressure Control

Robert H. Friedman, Lewis E. Kazis, Alan Jette, Mary Beth Smith, John Stollerman, Jeanne Torgerson, and Kathleen Carey

Am J Hypertens. 1996 Apr;9(4 Pt 1):285-92

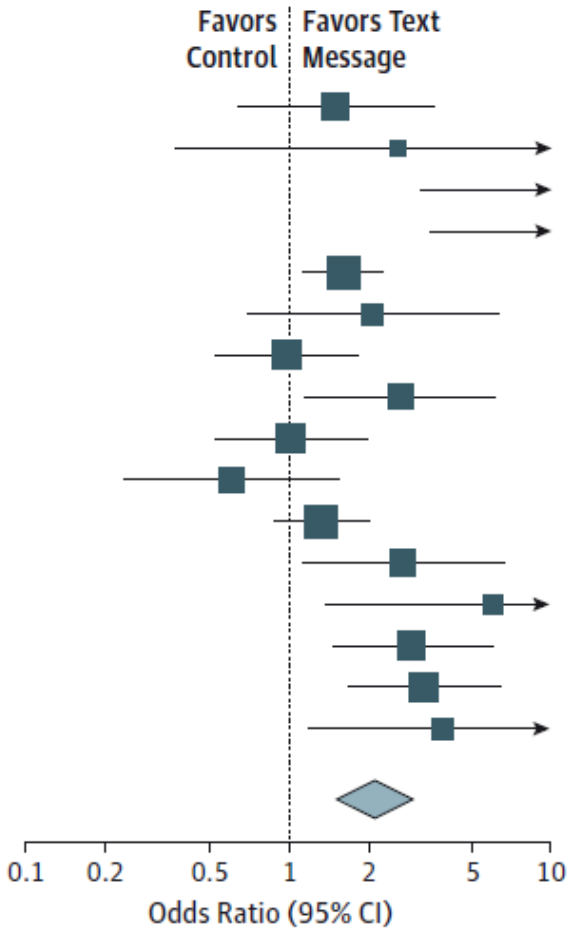
- 267 patients
- ≥ 60 yrs
- Weekly, subjects in the telephone group reported self-measured BP, knowledge and adherence to antihypertensive medication regimens, and medication side-effects to a computer-controlled telephone system

TABLE 3. CHANGE IN SYSTOLIC AND DIASTOLIC BLOOD PRESSURES BY STUDY GROUP*

	TLC	Usual Care	*P*
Adjusted mean systolic blood pressure change† (mm Hg)			
Total study population‡	11.5	6.8	.20
Nonadherent subjects§	12.8	0.9	.09
Adherent subjects§	10.3	12.8	.29
Adjusted mean diastolic blood pressure change† (mm Hg)			
Total study population‡	5.2	0.8	.02
Nonadherent subjects§	6.0	−2.8	.01
Adherent subjects§	4.5	4.4	.97

Systems for adherence (Mobile Telephone Text Messaging)

Source	Statistics for Each Study: Odds Ratio	(95% CI)	*P* Value
Márquez Contreras et al,[43] 2004	1.508	(0.631-3.605)	.36
da Costa et al,[29] 2012	2.571	(0.371-17.831)	.34
Hardy et al,[30] 2011[a]	21.131	(3.161-141.237)	.002
Khonsari et al,[31] 2015[a]	12.273	(3.405-44.236)	<.001
Lester et al,[32] 2010	1.612	(1.144-2.271)	.006
Lv et al,[21] 2012	2.074	(0.686-6.251)	.20
Lua and Neni,[33] 2013	0.985	(0.535-1.812)	.96
Maduka and Tobin-West,[34] 2013	2.644	(1.135-6.160)	.02
Mbuagbaw et al,[35] 2012	1.026	(0.519-2.026)	.94
Park et al,[36] 2014	0.610	(0.236-1.585)	.31
Pop-Eleches et al,[37] 2011	1.330	(0.882-2.005)	.17
Quilici et al,[38] 2013	2.705	(1.109-6.596)	.03
Strandbygaard et al,[39] 2010	6.018	(1.368-26.466)	.02
Vervloet et al,[40] 2012	2.959	(1.448-6.046)	.003
Wald et al,[41] 2014	3.267	(1.686-6.331)	<.001
Wang et al,[42] 2014	3.857	(1.180-12.606)	.03
Overall	2.107	(1.517-2.926)	<.001



[a] The text message intervention significantly improved adherence (odds ratio, 2.11; 95% CI, 1.52-2.93; *P* < .001). The effect remained significant after excluding 2 studies with extreme outcomes (Hardy et al[30] and Kohnsari et al[31]) (odds ratio, 1.78; 95% CI, 1.35-2.35; *P* < .001).

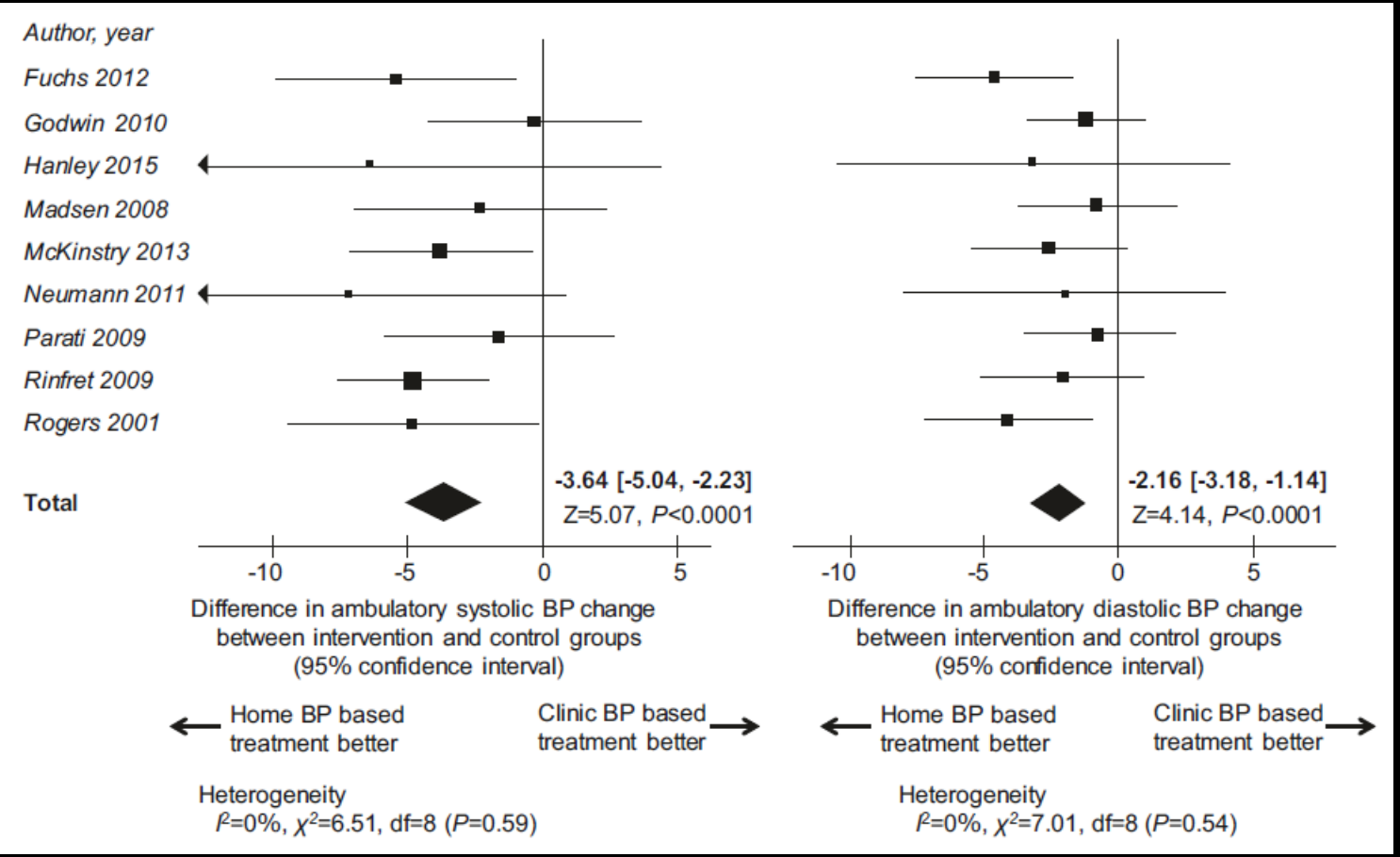
Thakkar J, et al. JAMA Intern Med. 2016 Mar;176(3):340-9

There's No Place Like Home to Diagnose Hypertension

- The **BP-CHECK study** was a 3-group, office, home, and kiosk BP monitoring for diagnosing hypertension.
- 510 adults with elevated BP without diagnosed hypertension
- Adherence to the **monitoring** regimen was:
  1. **home BP group (90.6%),**
  2. clinic group (87.2%),
  3. kiosk group (67.9%)
- From a patient-centered perspective, **home BP monitoring is the most acceptable method for diagnosing hypertension**

AHA. Hypertension Scientific Sessions 2021: Presentation 50. Presented September 29, 2021

HBP vs OBP for BP control



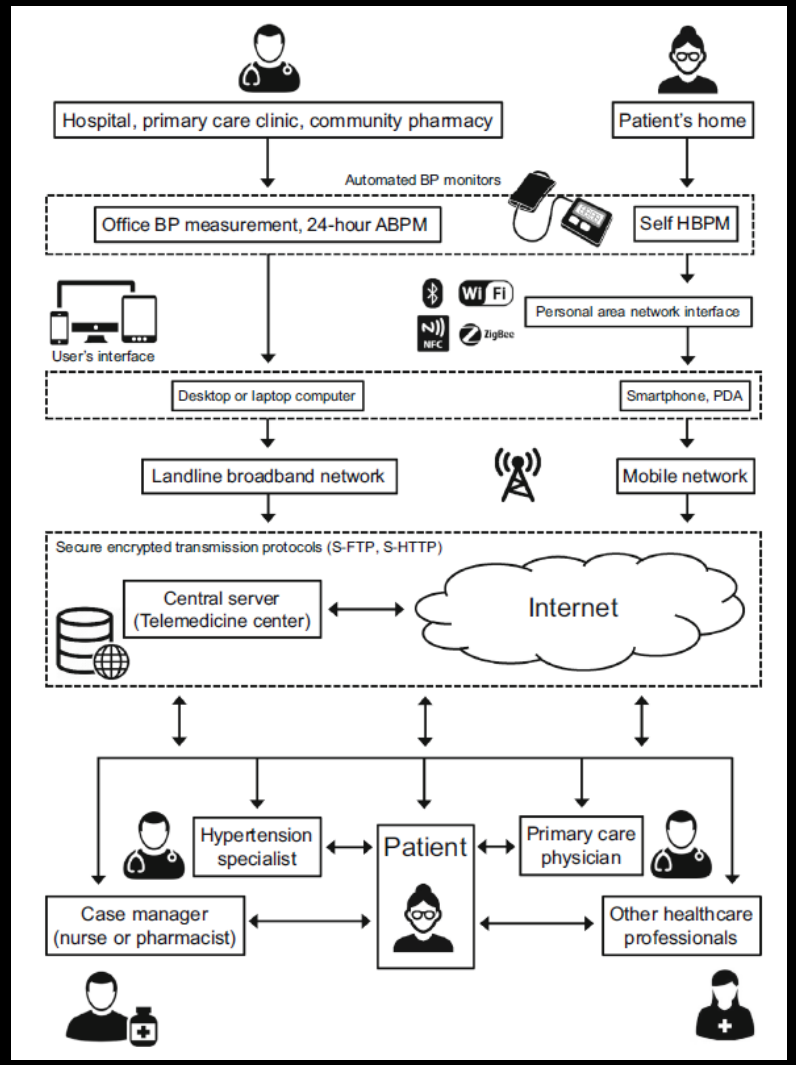
For outcomes of cardiovascular events and related deaths, there are no appropriate studies

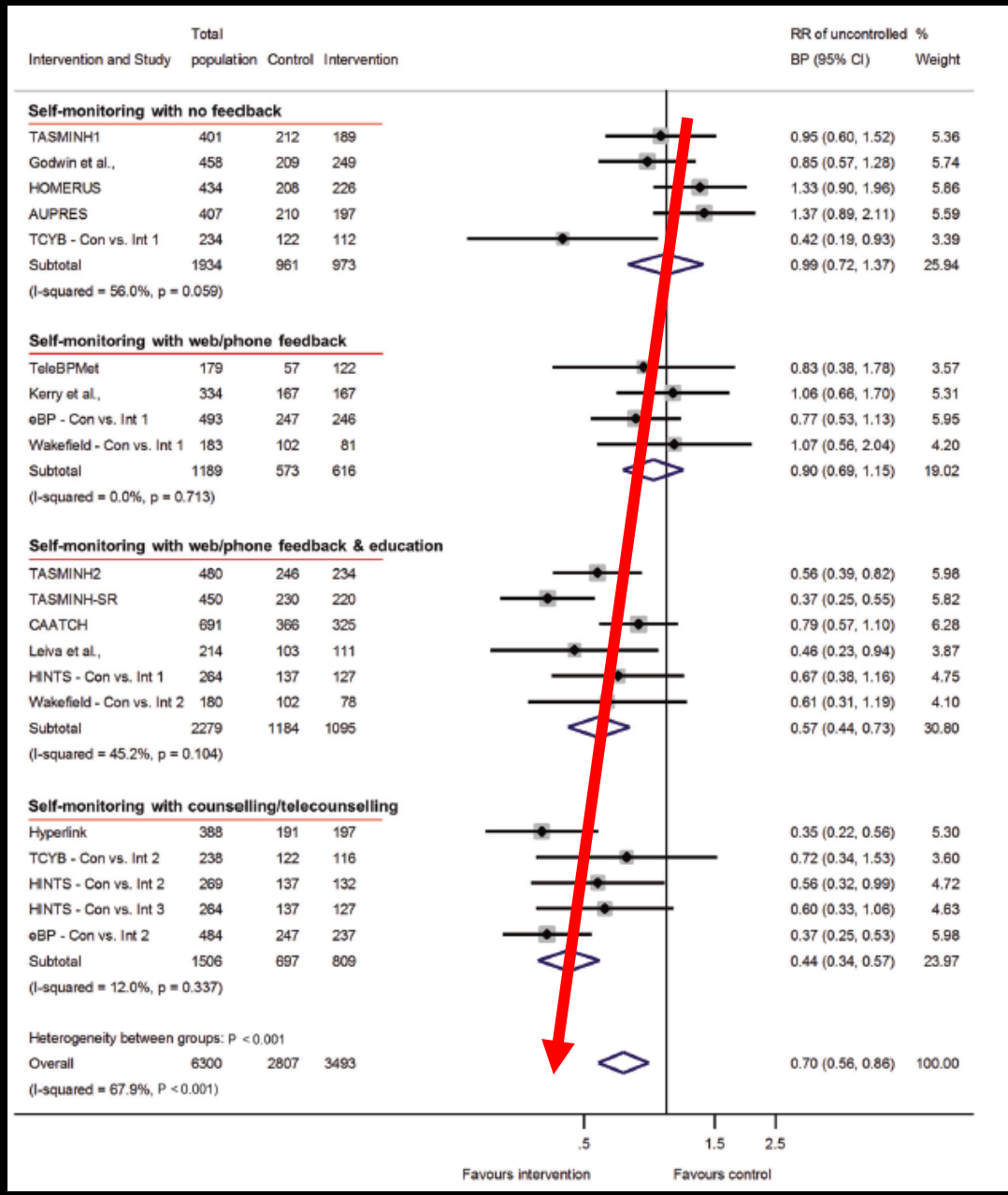
HBPM:

- evaluate the patients' BP,
- the antihypertensive effects,
- the seasonable and day-to-day BP variation during treatment in the long term,
- considered useful for improving patients' adherence

Satoh M, et al. Hypertens Res. 2019 Jun;42(6):807-816

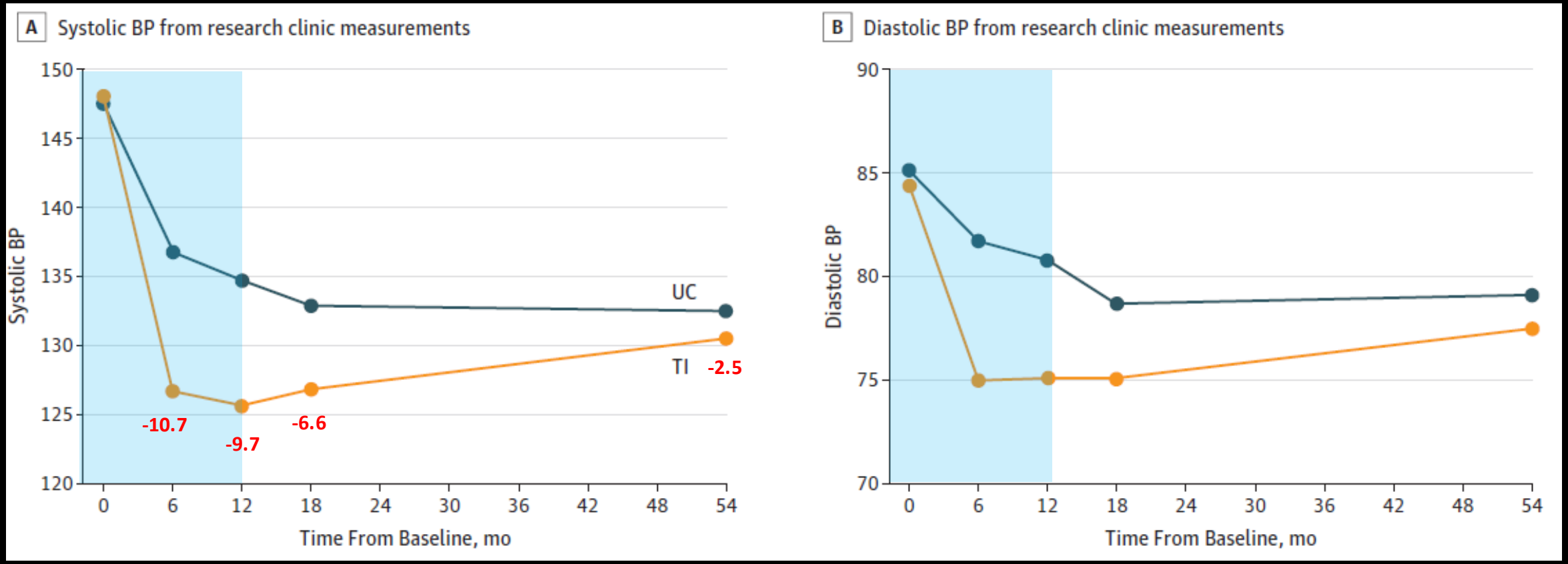
It’s a matter of intervention





Pellegrini D, et al. Hypertens Res. 2020 Jul;43(7):621-628

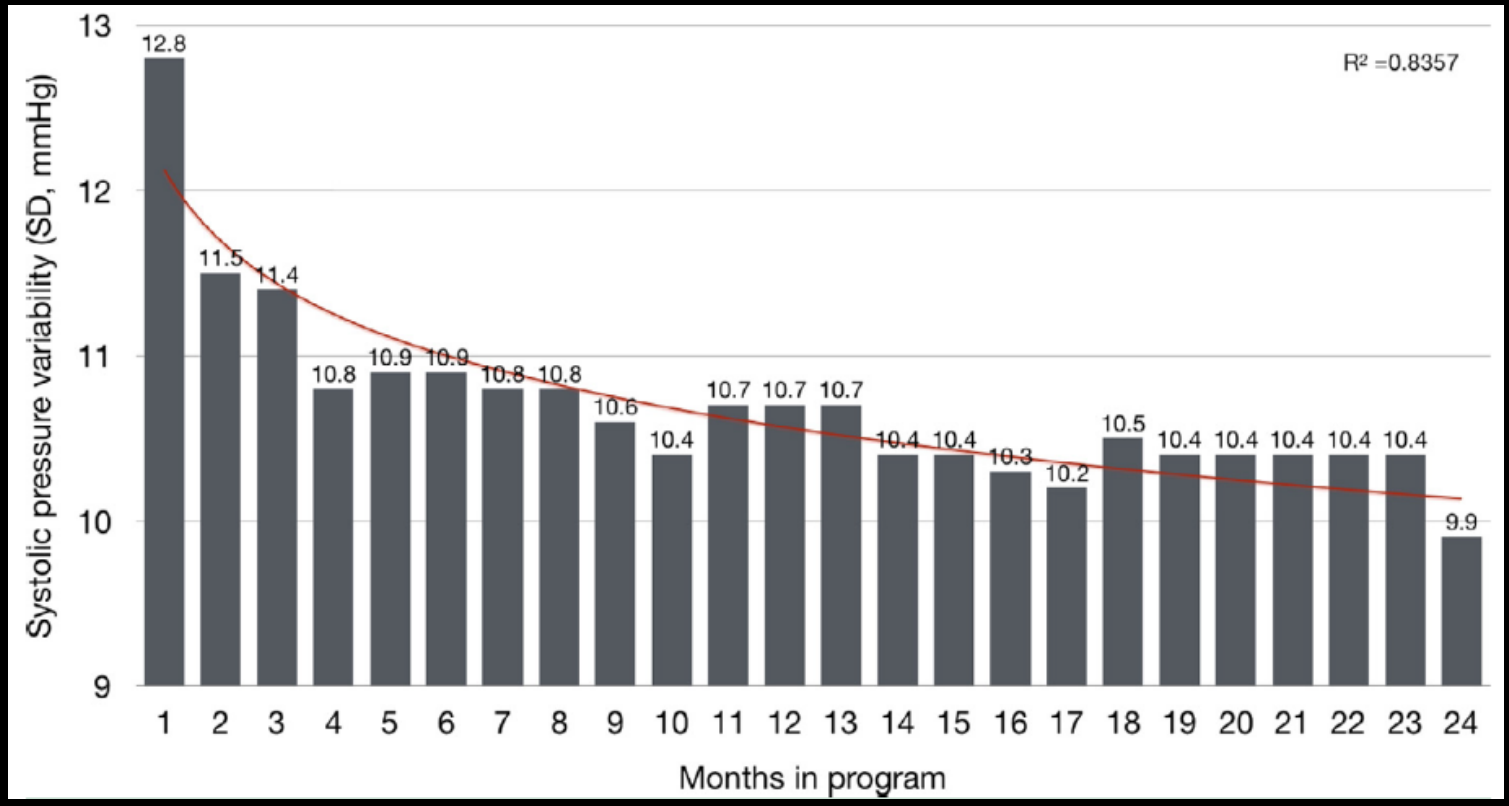
The long term effect



Margolis KL, et al. JAMA Netw Open. 2018 Sep 7;1(5):e181617

Telemedicine Improves BP Variability

- 803 hypertensive patients
- Mean age 67 ± 12 yrs
- Reduction of 8 mmHg for the SBP and 5 mmHg for the DBP



Milani RV, et al. Am J Med. 2020 Jul;133(7):e355-e359

Is it safe?

- Telemedicine group used a 3G network–attached HBP monitoring device, consulted hypertension specialists from an academic hospital through web-based video visits

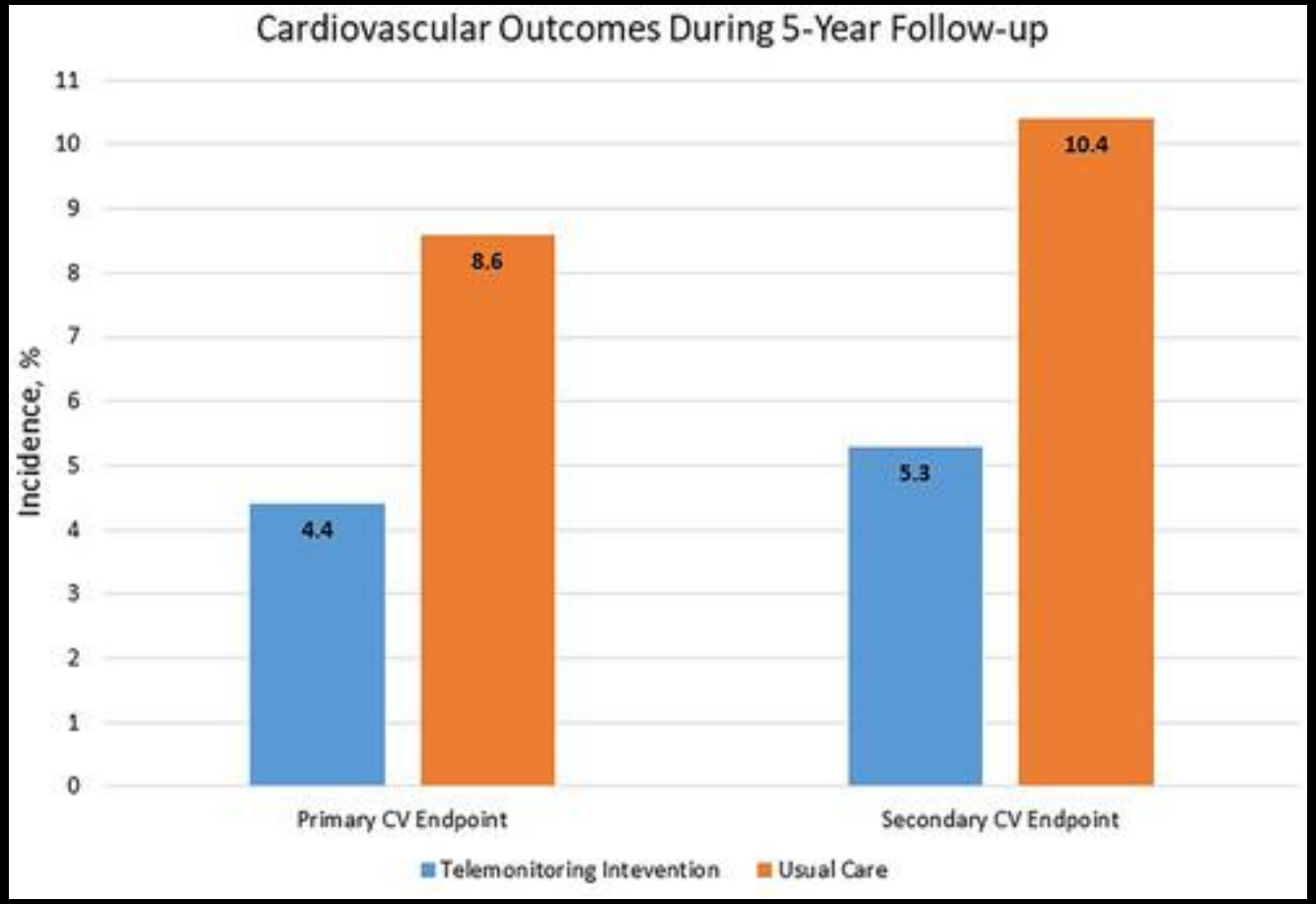
Table 3. Home blood pressure change from baseline till the end of the 1-year study period.

	Usual care group	Telemedicine group	*P* value
Change in systolic blood pressure (mmHg), mean (SD)	–5.4 (11.3)	–9.2 (14.3)	.23
Change in diastolic blood pressure (mmHg), mean (SD)	–3.5 (8.1)	–5.5 (8.7)	.33

- Rate of SBP control (135 mmHg) was better in the telemedicine group (85.3% vs 70.0%; P=.01)
- Significant adverse events were not observed
- Telemedicine without actual office visits was determined to be relatively safe in managing hypertension for 1 year

Yatabe J, et al. JMIR Cardio. 2021 Aug 31;5(2):e27347

What about CV events?



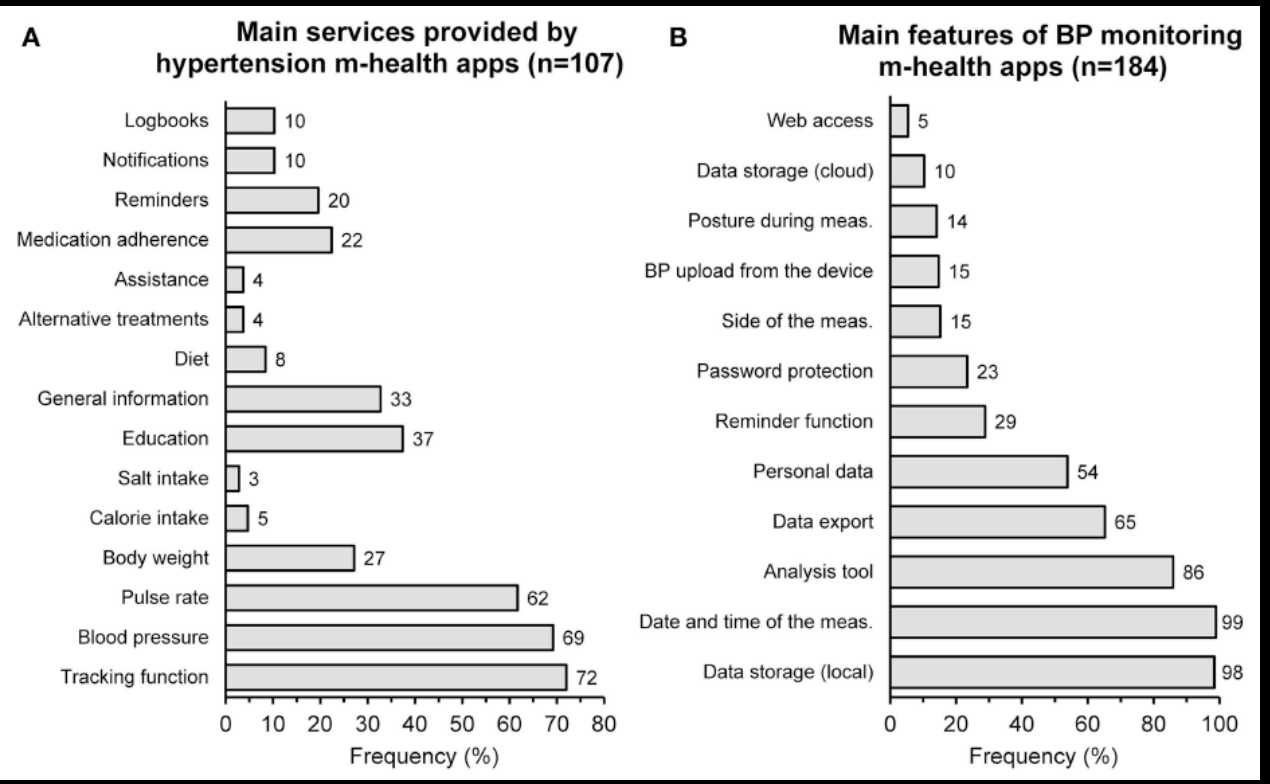
	Intervention (n=228)		Usual Care (n=222)	
Type of Event	Events, N	Patients, N (%)	Events, N	Patients, N (%)
MI	5		11	
Stroke	4		12	
Heart failure	5		3	
CV Death	1		0	
Total Events	15	10 (4.4%)	26	19 (8.6%)
Revascularization	2		10	
Total Events	17	12 (5.3%)	36	23 (10.4%)

Intervention costs were $1,511 per patient.

Over 5 years, estimated event costs were $758,000 in the TI group and $1,538,000 in the UC group for a return on investment of **126%** and a net cost savings of about $1,900 per patient.

Margolis KL, et al. Hypertension. 2020 Oct;76(4):1097-1103

The Apps m-health in HTN

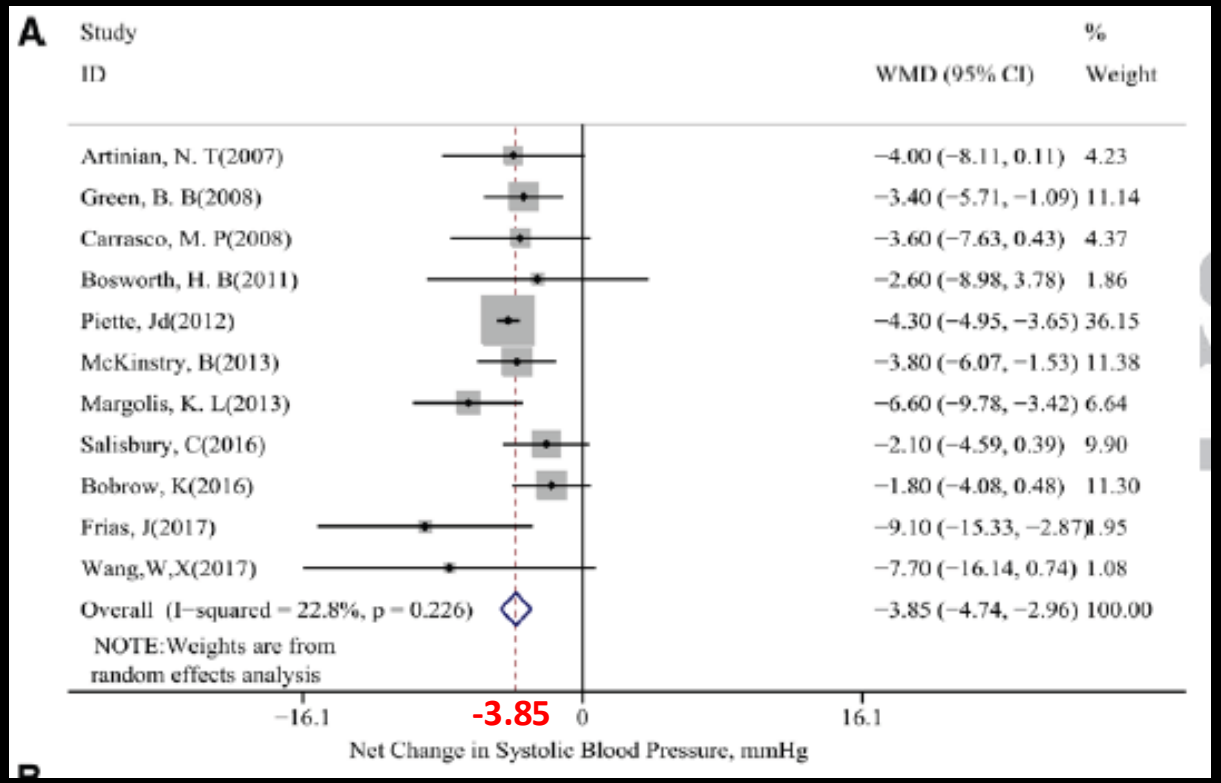


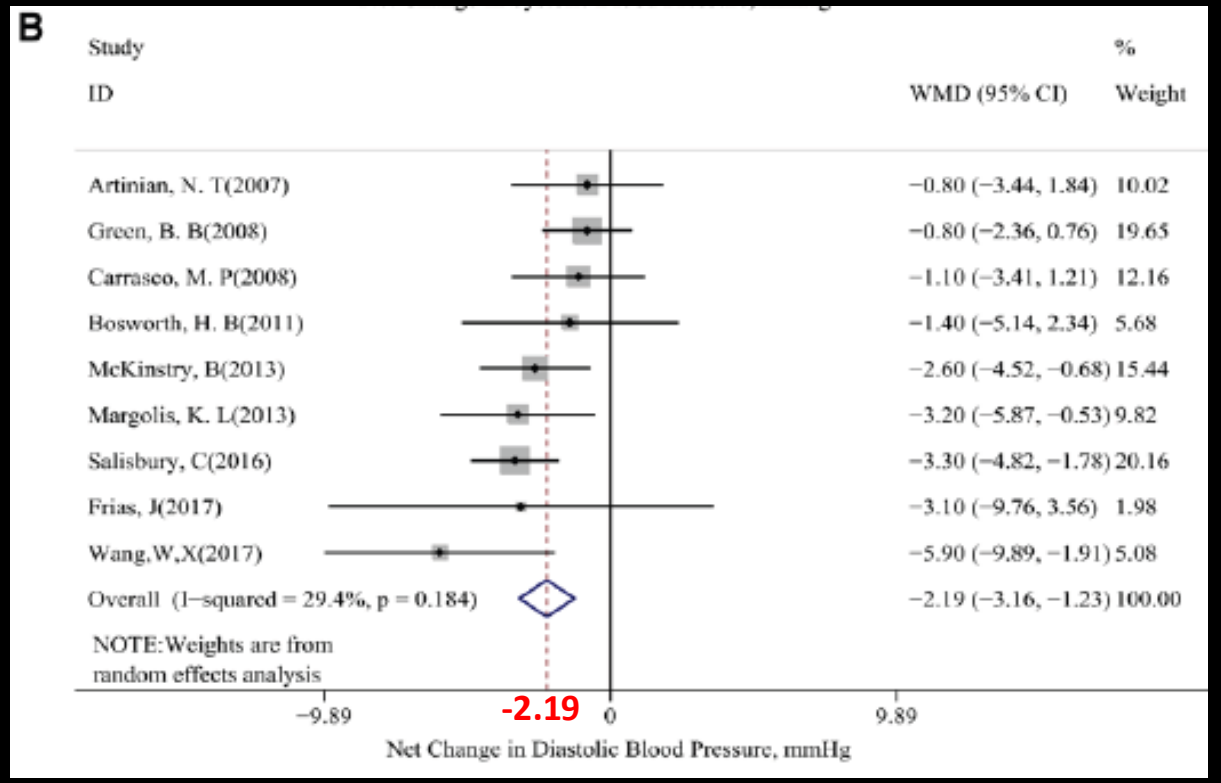
Omboni S. Front Cardiovasc Med. 2019 Jun 13;6:76

Study	Functionalities					
	Self-monitoring	Use of prompt/cues (reminder and alert)	Educational information	Communication with others	Automatic feedback	Stress management
Anglada-Martínez et al [39]	✓	✓	✓	✓	✓	—
Bengtsson et al [36]	✓	✓	—	—	✓	—
Bengtsson et al [37]	✓	✓	—	—	✓	—
Hallberg et al [38]	✓	✓	—	—	✓	—
Carrera et al [40]	✓	✓	✓	✓	✓	—
McGillicuddy et al [25]	✓	✓	—	—	✓	—
McGillicuddy et al [26]	✓	✓	—	—	✓	—
Davidson et al [24]	✓	✓	—	—	✓	—
McGillicuddy et al [27]	✓	✓	—	—	✓	—
Bloss et al [28]	✓	✓	✓	✓	✓	—
Patel et al [29]	✓	✓	✓	—	—	—
Or and Tao [42]	✓	✓	✓	—	✓	—
Logan et al [33]	✓	✓	—	—	✓	—
Petrella et al [34]	✓	✓	—	—	—	—
Albini et al [41]	✓	✓	✓	—	—	—
Mao et al [31]	✓	✓	✓	✓	—	—
Moore et al [30]	✓	—	—	✓	✓	—
Mendelson et al [35]	✓	—	✓	—	—	—
Kang et al [44]	✓	✓	✓	—	✓	—
Sun et al [43]	✓	—	—	—	—	—
Banerjee et al [32]	✓	✓	—	✓	✓	✓

Alessa T, et al. JMIR Mhealth Uhealth. 2018 Jul 23;6(7):e10723

The mHealth intervention on BP





Lu X, Hypertension. 2019 Sep;74(3):697-704

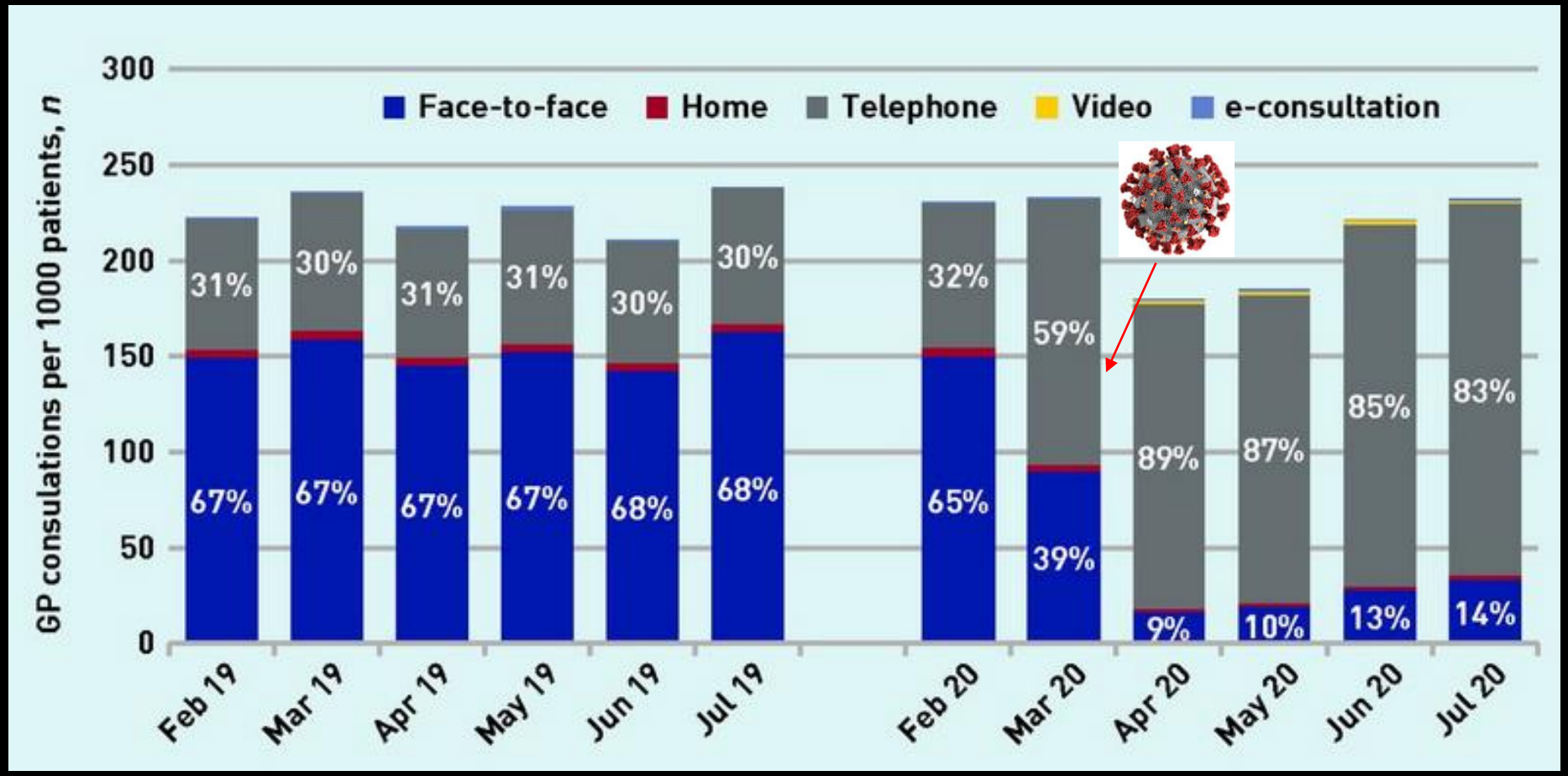
21.6 Use of telemedicine and tele-health technologies

The advent of new technologies has allowed use of internet-based interactive digital interventions (tele-health) and health-related mobile applications that can also be installed on smartphones. This enables, at least in perspective, virtual care of hypertension [139]. The COVID-19 pandemic highlighted the role of remote management of chronic conditions and greatly contributed to the familiarization of both patients and physicians with these new technologies [17,139].

Interactive digital interventions include behavioral aids and promotional material for hypertension self-management. Several studies and meta-analyses suggest that these interventions are associated with better patient education, greater BP reduction and even reduced CV outcomes [1695–1697]. Mobile applications include the assessment of heart rate, thereby recognizing AF, sleep quality, physical activity and even cuff-less BP measurement [62,1698]. Transmission of HBPM, or even additional data obtained by physician are under investigation by many studies, including those promoted by ESH [1699,1700]. At present, it is premature to reach a conclusion on the benefits of these technologies, and the virtual management approach in general. Nevertheless, favorable data on home BP telemonitoring have been obtained. A meta-analysis of 46 RCTs in about 14 000 hypertensive patients revealed that home BP telemonitoring is associated with significant BP reduction and improved BP control [1701]. Similar results were reported by others [139,1702] including a study during the COVID-19 pandemic [1621].

COR	LOE	Recommendation
IIa	A	1. Telehealth strategies can be useful adjuncts to interventions shown to reduce BP for adults with hypertension.[S12.3.2-1–S12.3.2-5]

Hypertension management in the COVID era



Murphy M, et al. Br J Gen Pract. 2021 Feb 25;71(704):e166-e177

Not any war plan resist to enemy plans (Napoleon): COVID has changed our prespectives

American Heart Association Invites Applications for Health Equity Research Network on Prevention of Hypertension

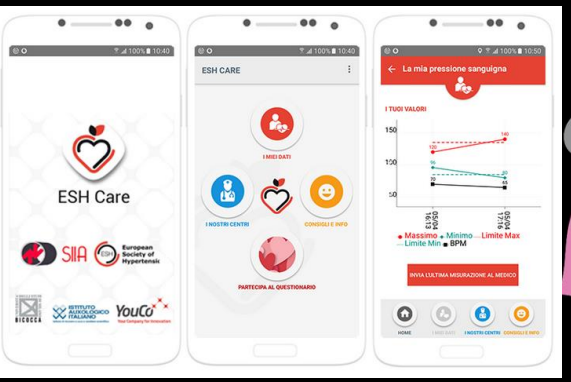
April 13, 2021

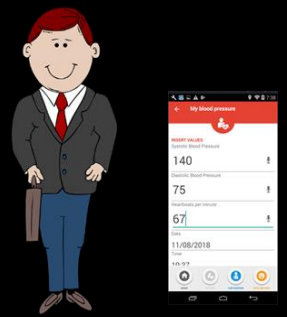
Deadline: May 13, 2021

European Society of Hypertension

ESH CARE extension platform

ESH CARE App and its extension platform

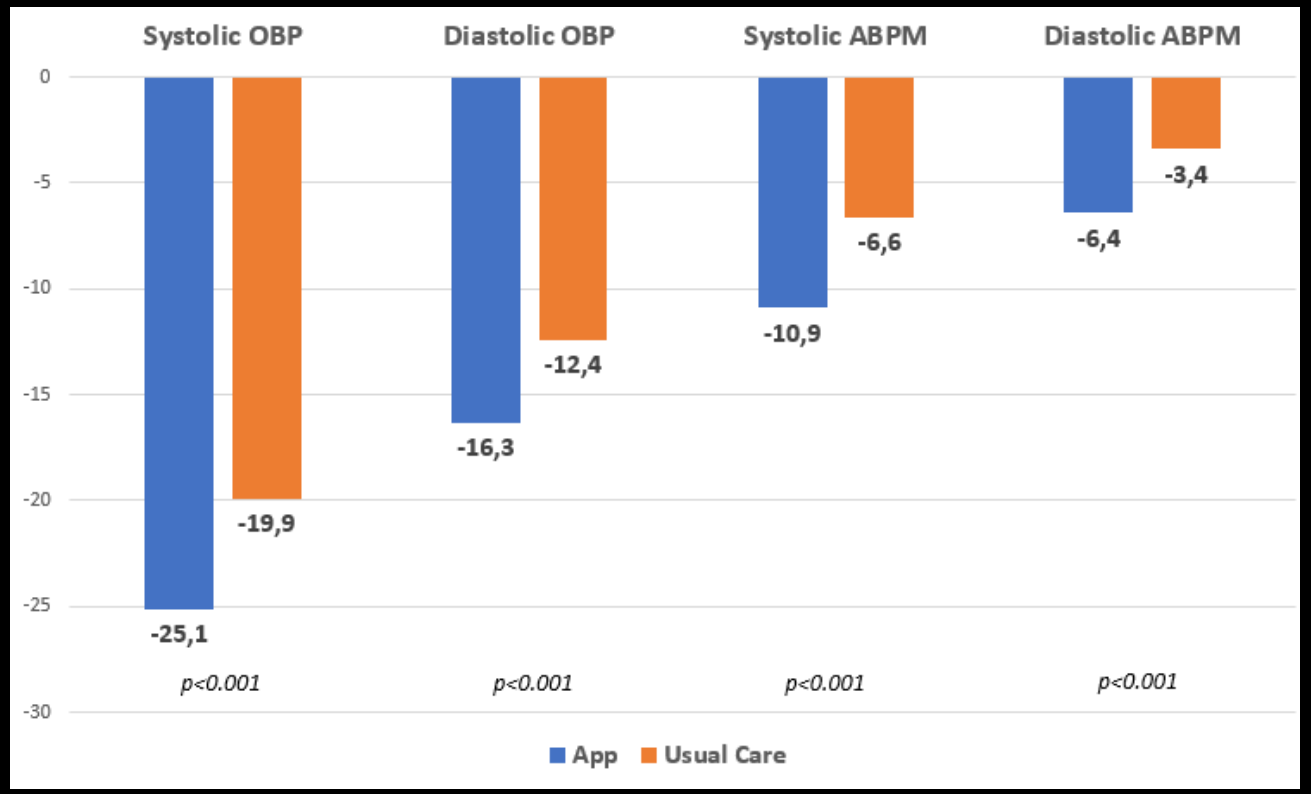


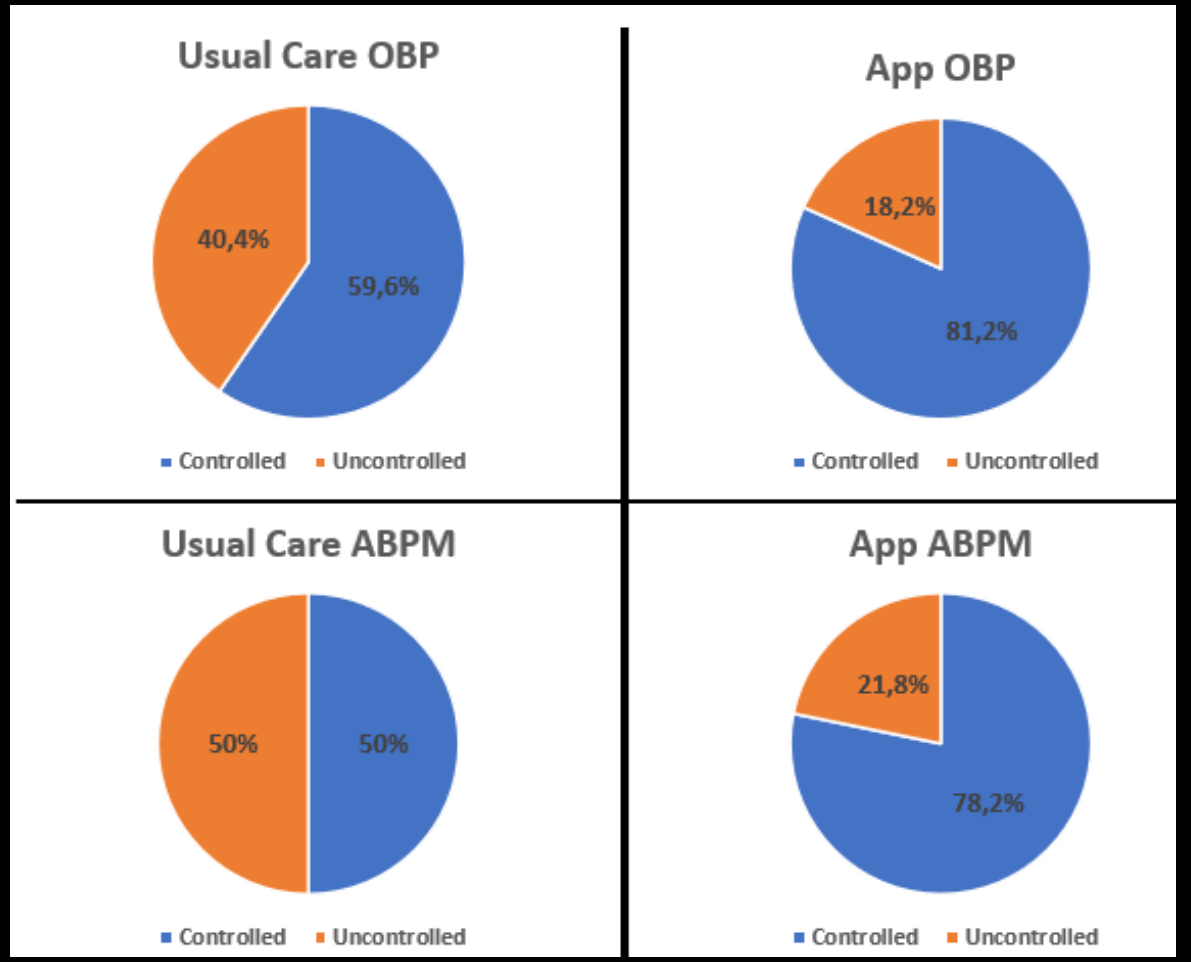


- Overview of each doctor's patients recent BP data
- Statistics for each patient BP data (average BP, percentage above normal values, etc.)

- Notifications/alerts for each doctor for extreme BP values

BP control with the ESH CARE App

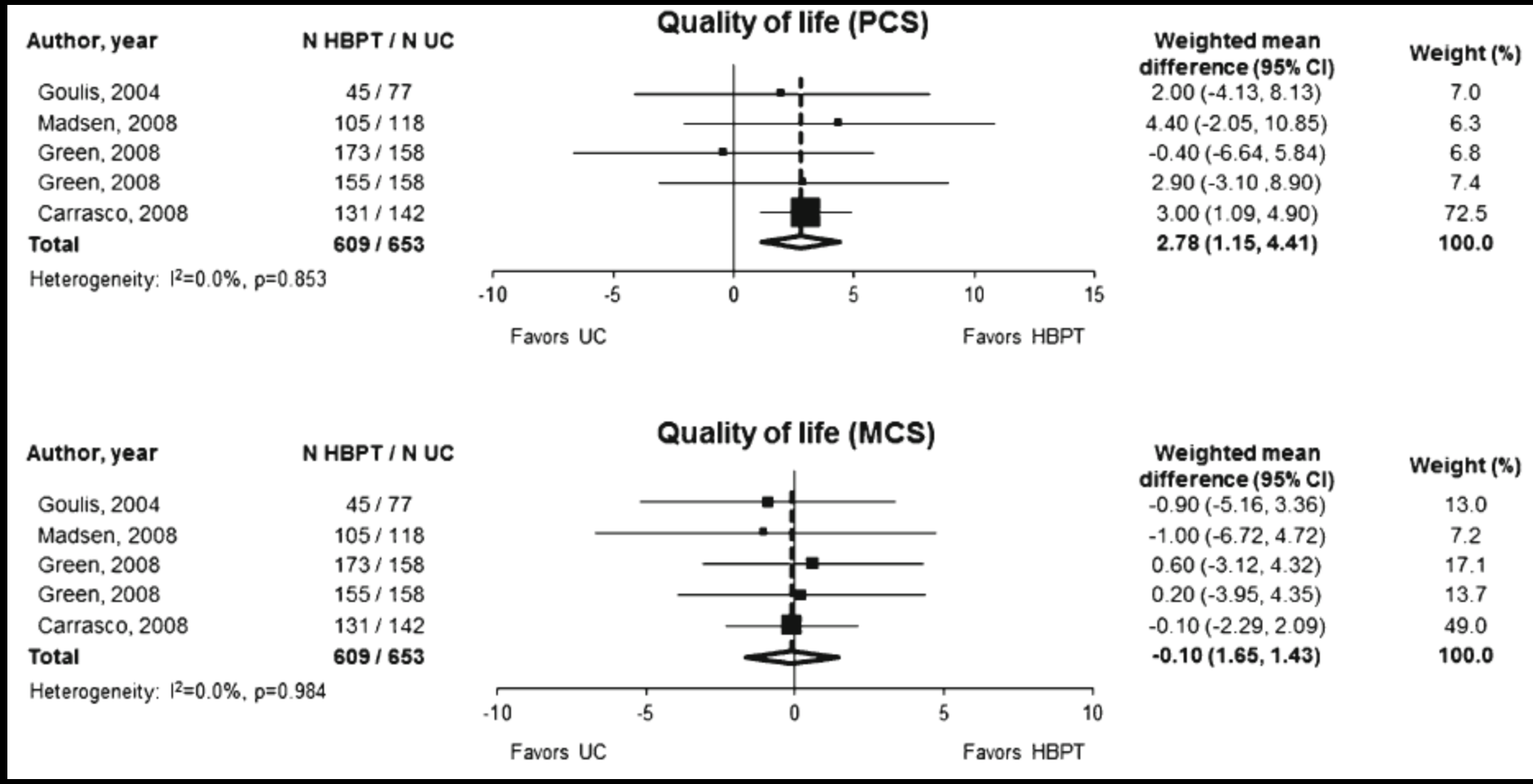




Konstantinidis D, et al. Eur J Prev Cardiol. 2025 Apr 24:zwaf240

The patients' perception

- In 10 studies, including 1,120 patients, 87.1% of the participants regarded the BPT technique as useful to manage their condition.



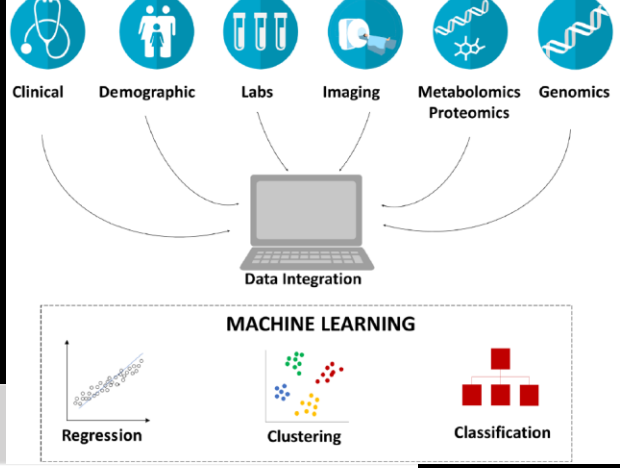
Omboni S, et al. Curr Hypertens Rep. 2015 Apr;17(4):535

The physicians' perception

- Only **25%** of doctors recommend the use of m-health
- **42%** of doctors worry that m-health apps **will make patients too independent**
- **58%** believe that telemedicine **will play a significantly greater role in the future**
- Allows to reach distant patients and increase the number of served patients
- There are no standardized methods for the quality evaluation of m-health apps
- The lack of adequate infrastructures, lack of reimbursement

Omboni S. Front Cardiovasc Med. 2019 Jun 13;6:76

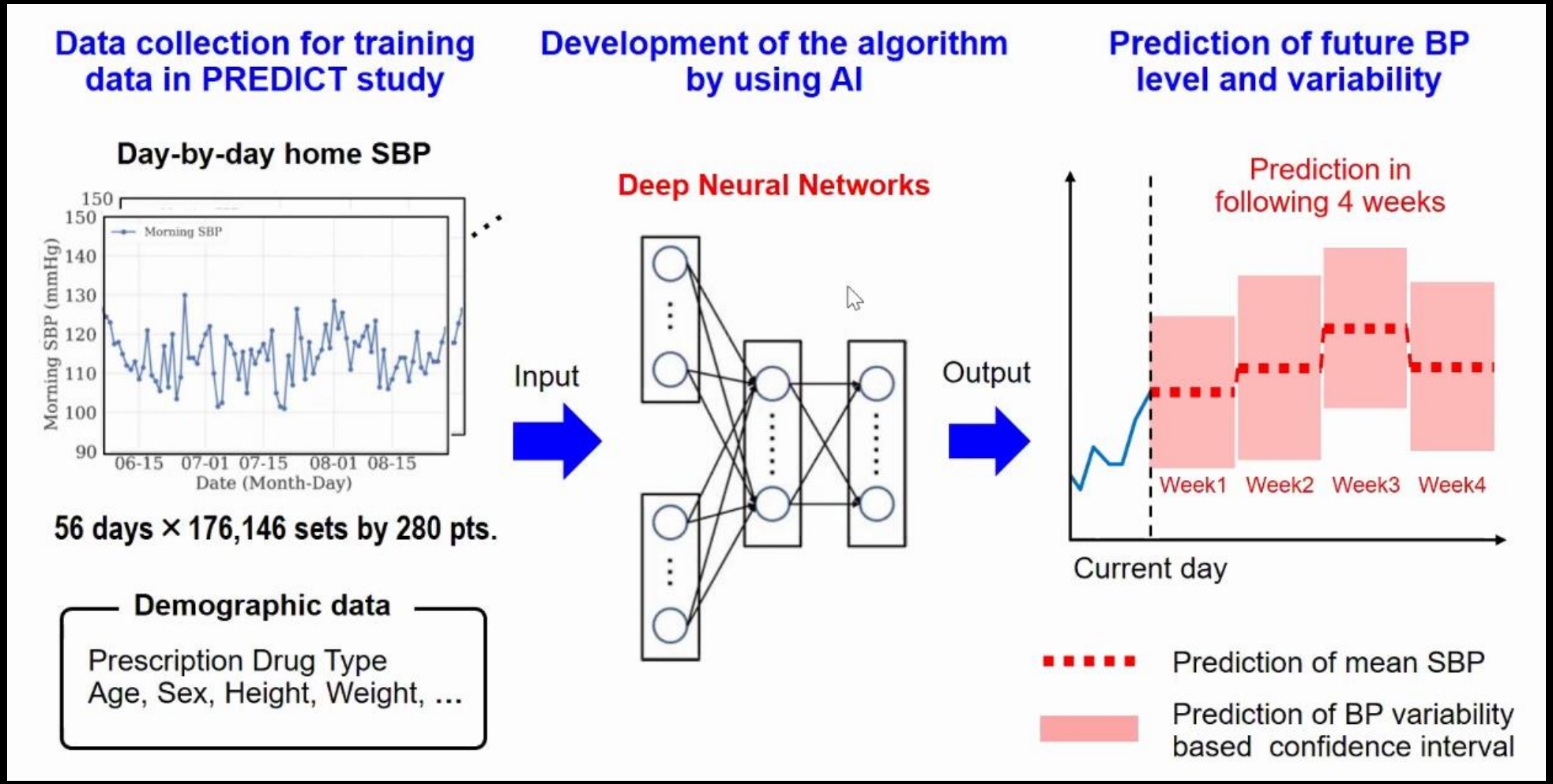
AI applications and new technology for HTN management



Applications	AI Techniques	Benefits
Prediction:		
1) Identification of hypertension	Classification tree[12], Artificial neural network (ANN)[13], k-nearest neighbors algorithm (KNN)[14]	Precision diagnosis
2) Incidence prediction	Data mining with Bayesian Network[15], Extreme gradient boosting (XGBoost)[16,17]	Timely intervention
3) Clinical outcome prediction	Random Forest[18], XGBoost[19]	Treatment plan adjustment
Management:		
1) Treatment effectiveness	Ensemble Model[28], X-Learner[29], Support Vector Regression (SVR)[30]	Personalized treatment plan
2) Blood pressure variability	Deep neural network with gated recurrent unit[31], K-means clustering[32]	Pre-emptive interventions (eg lifestyle modifications) for normotensive people
New technology for blood pressure measurement	Convolutional Neural Network (CNN)[34], Random Forest[35], Long short-term memory (LSTM)[36,37], recurrent neural (RNN)[40], Advance machine learning algorithms[41]	Self BP monitoring for hypertension

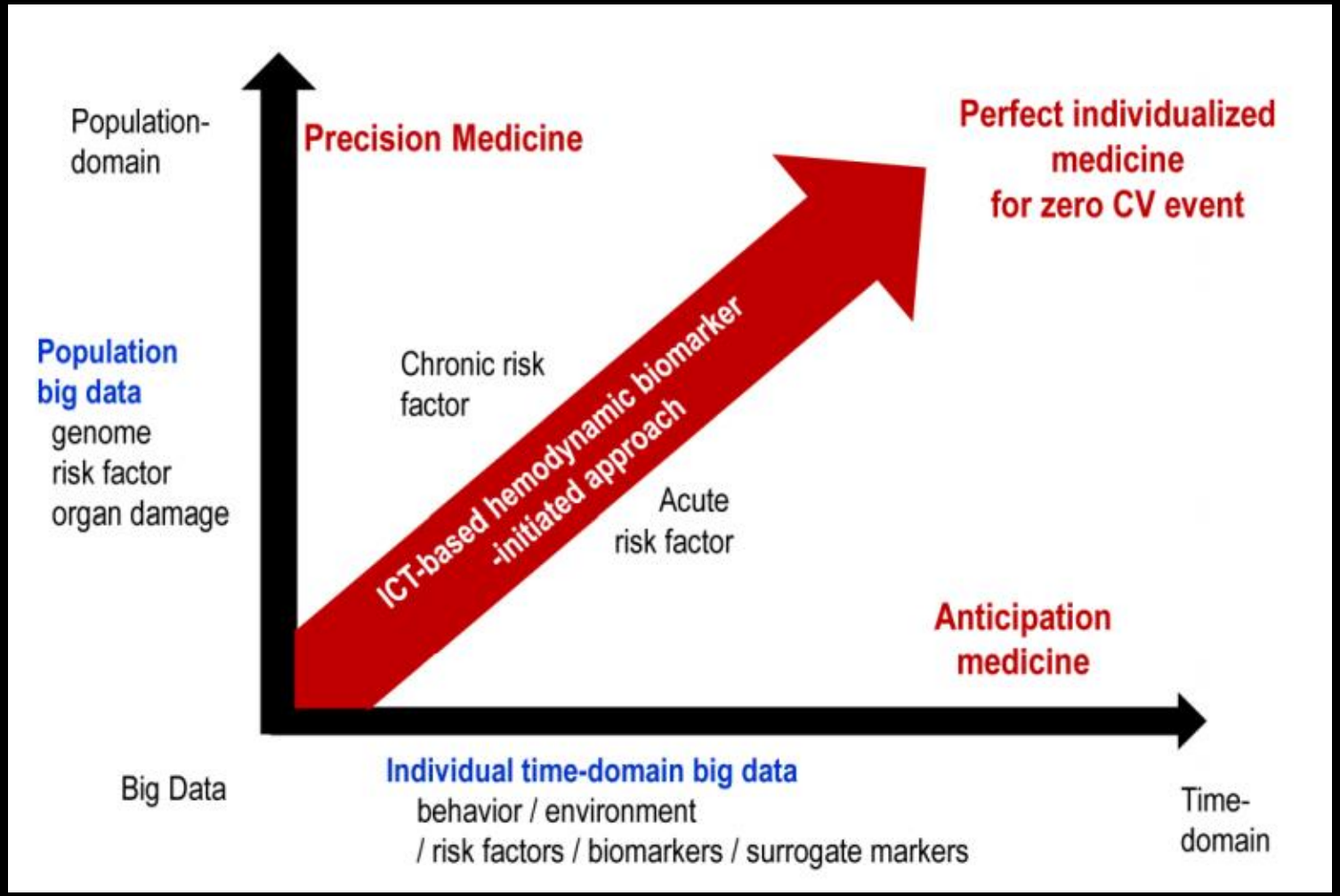
Tsoi K, et al. J Clin Hypertens (Greenwich). 2021 Mar;23(3):568-574

Prediction of BP Variability using Artificial Intelligence (AI)



Koshimizu, et al. Intern J Medical Inform 2020; 126: 104067

Anticipation medicine of CV disease



Kario K, et al. Prog Cardiovasc Dis. 2017 Nov-Dec;60(3):435-449

Support to GP and patients…

- This study evaluates the effectiveness of the newly developed PIA (Pc supported case management of hypertensive patients to implement guideline-based hypertension therapy using a physician-defined and -supervised, patient-specific therapeutic algorithm) intervention with PIA-ICT and eLearning for general practices.

	All (N = 525)	Intervention group (n = 265)	Usual care group (n = 260)	P value[a]
SBP (mmHg), M1, mean (SD)	138.6 (17.3)	136.0 (16.4)	141.3 (17.8)	<0.001
Controlled SBP (mmHg), M1, N (%)	282 (53.7%)	173 (65.3%)	109 (41.9%)	<0.001
DBP (mmHg), M1, mean (SD)	84.5 (11.0)	84.1 (10.9)	84.9 (11.1)	0.40
Controlled DBP (mmHg), M1, N (%)	361 (68.8%)	194 (73.2%)	167 (64.2%)	0.03
SBP (mmHg), M2, mean (SD)	136.0 (15.1)	134.3 (14.5)	137.8 (15.5)	0.01
Controlled SPB (mmHg), M2, N (%)	323 (61.5%)	192 (72.5%)	131 (50.4%)	<0.001
DBP (mmHg), M2, mean (SD)	83.3 (10.1)	83.1 (9.7)	83·4 (10.6)	0.73
Controlled DBP (mmHg), M2, N (%)	387 (73.7%)	206 (77.7%)	181 (69.6%)	0.04
BP, M1, N (%)	242 (46.1%)	149 (56.2%)	93 (35.8%)	<0.001
Primary endpoint: BP M2, N (%)	282 (53.7%)	166 (62.6%)	116 (44.6%)	<0.001

BP M1 = first measurement after 5 min rest; BP M 2 = second measurement after 1 min; DBP = Diastolic blood pressure; SBP = Systolic blood pressure. [a]z-Test.

Leupold F, et al. EClinicalMedicine. 2022 Nov 3;55:101712

Blood pressure measurement

William Harvey
An Anatomical Exercise on the Motion of the Heart and Blood in Living Beings

1628

Carl Ludwig
Κυματογράφος
Kymograph

1847

Samuel Siegfried Karl Ritter von Basch
Μανόμετρο

1881

Nikolai Korotkoff
Ήχοι ροής αίματος

1905

1733

Reverend Stephen Hales
Μέτρηση της πίεσης (άλογο)

1855

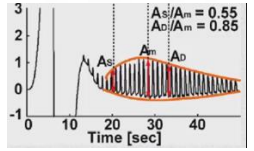
Karl Vierordt
Περιχειρίδα – εξάλειψη παλμού

1896

Scipione Riva-Rocci
Υδραργυρικό σφυγμομανόμετρο

1974

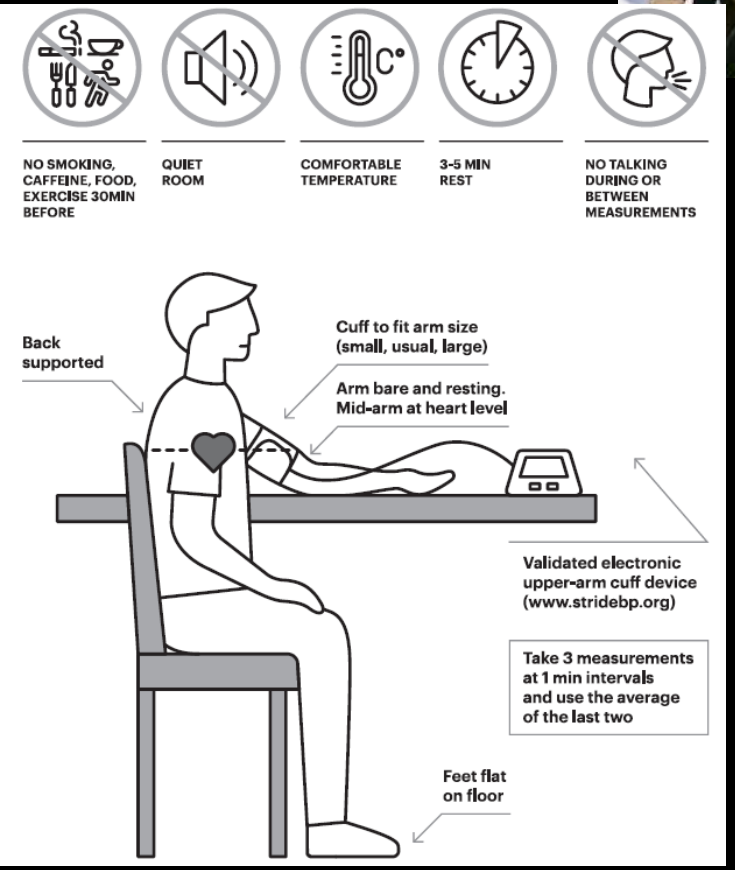
Panasonic
Αυτόματο ταλαντωσιμετρικό πιεσόμετρο



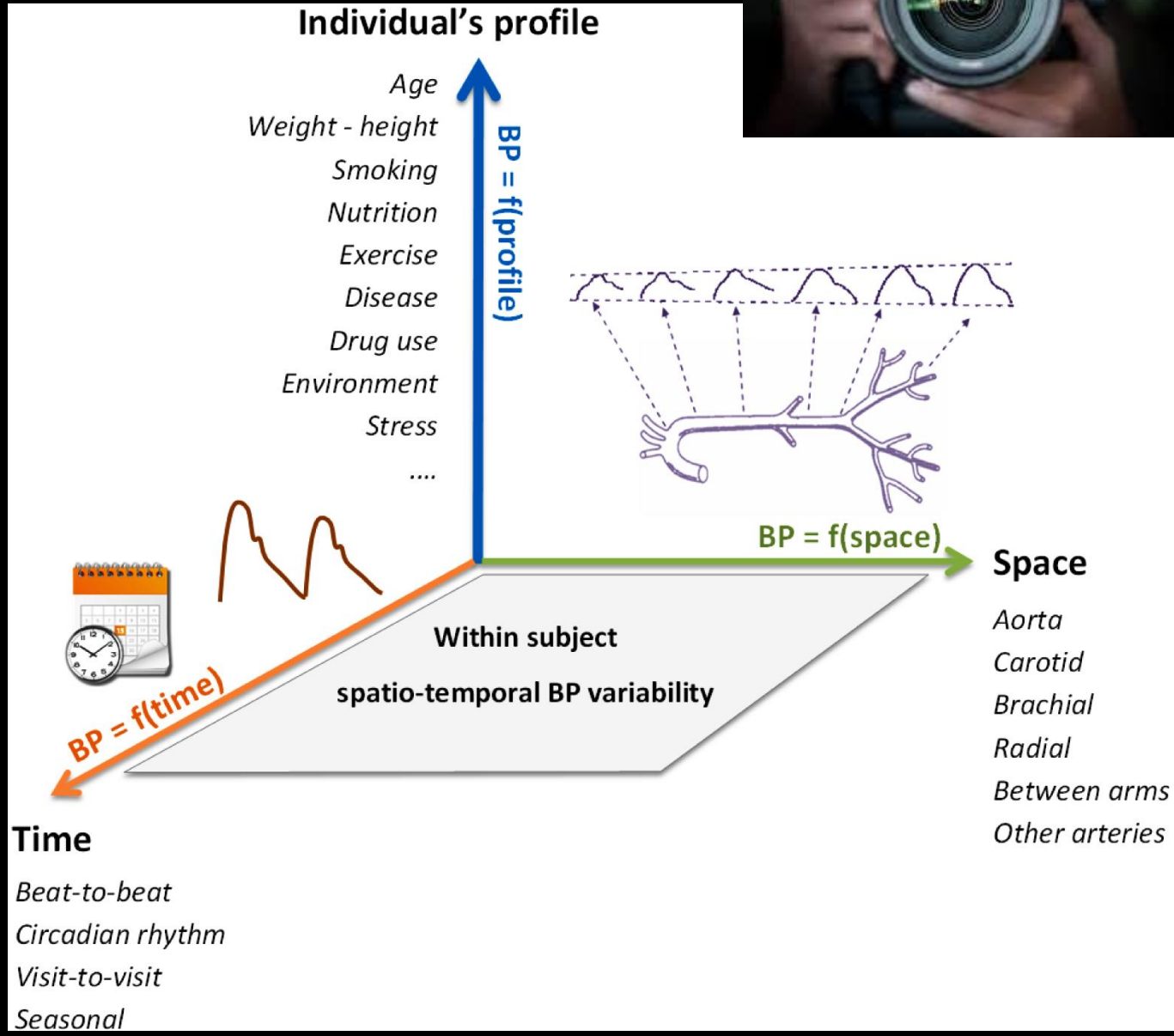
"The measurement of BP is likely the clinical procedure of greatest importance that is performed in the sloppiest manner"

Norman Kaplan 1998

When, Where, How?



"The dynamic behavior of BP has been largely ignored, and focus put on snapshot BP measurement"



Stergiou GS, et al. J Hypertens. 2021 Mar 11

Papaioannou TG, et al. Curr Pharm Des. 2015;21(6):697-9

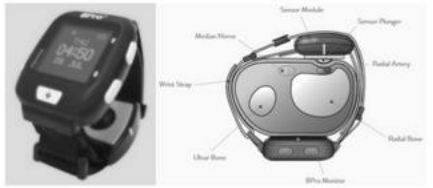
REVIEW ARTICLE

Check for updates

Wearable blood pressure measurement devices and new approaches in hypertension management: the digital era

D. Konstantinidis[1]✉, P. Iliakis[1], F. Tatakis[1], K. Thomopoulos[2], K. Dimitriadis[1], D. Tousoulis[1] and K. Tsioufis[1]

Omron
HEM-6410T



BPro, HealthSTATS International

Finometer

CareUp R
smartwatch

Portapres

InstaBP
application

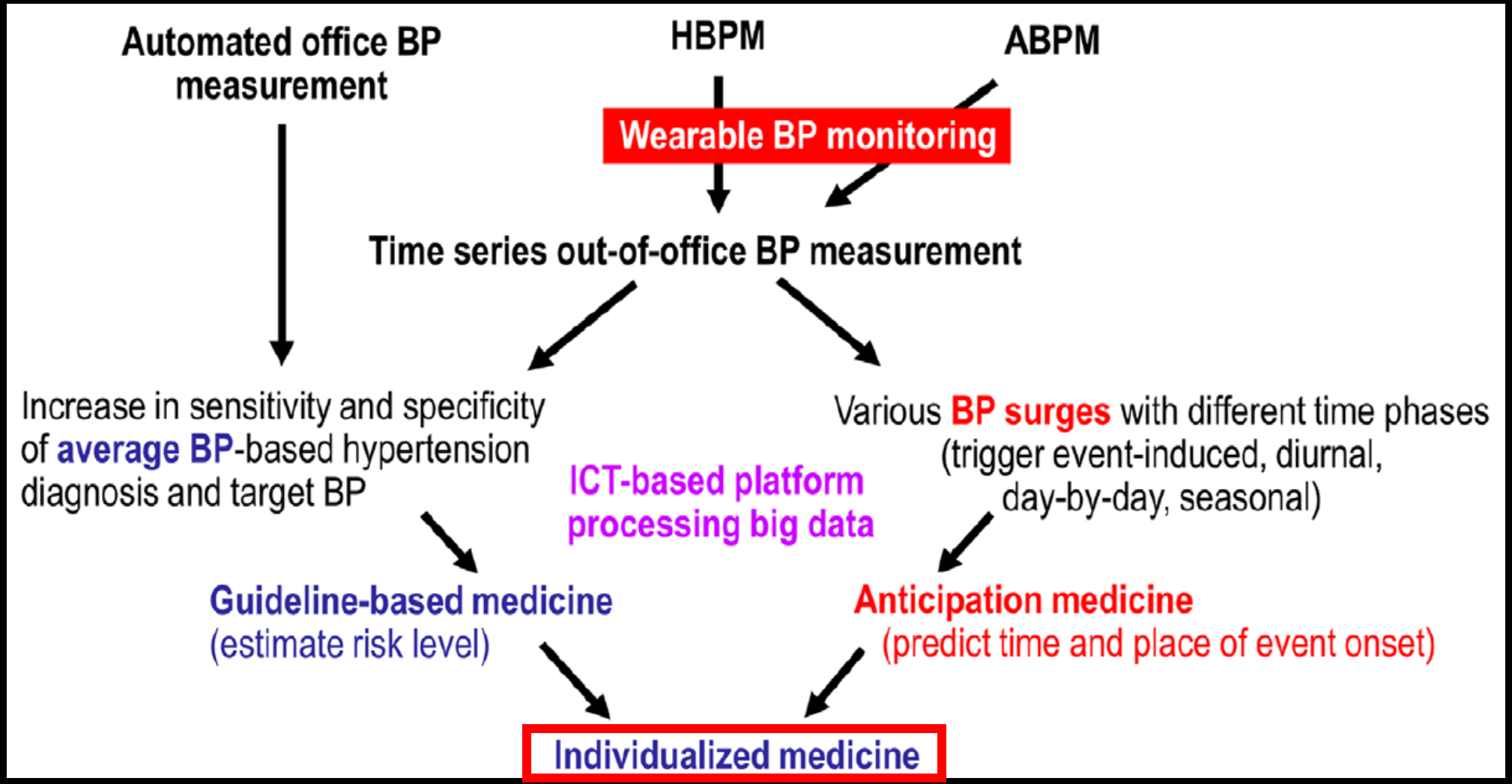
J Hum Hypertens. 2022 Mar 23:1–7

Uses and utilities that wearable BP monitors have the potential to support

	Clinical use	Office BP	Home BP	Ambulatory BP	Pharmacy BP	Wearable Persistent BP
Individual scale 	Screening	+++[a]	+[a]	-[a]	++[a]	✓
	Initial diagnosis	+[a]	++[a]	+++[a]	-[a]	✓
	Initial phenotyping			++[b]		✓
	Treatment titration based on thresholds	+[a]	++[a]	++[a]	-[a]	✓
	Treatment titration based on individual dynamic phenotyping			++[c]		✓
	Follow-up	++[a]	+++[a]	+[a]	+[a]	✓
Population scale 	Screening of communities	++[d]	+++[e]		+++[f]	✓
	Phenotyping of communities					✓
	Titration of public health interventions				+++[f]	✓

Sola J, et al. Sci Rep. 2021 Oct 19;11(1):20644

Wearable devices for HTN management



Kario K. Hypertension. 2020 Sep;76(3):640-650

Wearable devices

Types

- Wrist-cuff devices
- Cuffless (wrist band)

Methodology

- Oscillometry (wrist cuff)
- Applanation tonometry, photoplethysmography, pulse transit time, other

ORIGINAL PAPER

WILEY

Validation of a wrist-type home nocturnal blood pressure monitor in the sitting and supine position according to the ANSI/AAMI/ISO81060-2:2013 guidelines: Omron HEM-9600T

Mitsuo Kuwabara PhD[1,2] | Kanako Harada MPH[2] | Yukiko Hishiki BA[2] | Kazuomi Kario MD, PhD[1]

J Clin Hypertens (Greenwich). 2019 Apr;21(4):463-469

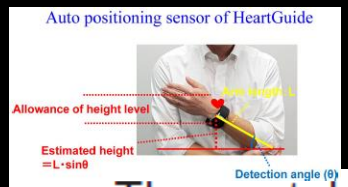
supine with downwards palm position, respectively. In conclusion, the Omron HEM-9600T in the sitting position fulfilled the validation criteria of the ANSI/AAMI/ISO81060-2:2013 guidelines. On the other hand, the accuracies of HEM-9600T in the supine position differed depending on the positioning of the palm, with only the downwards palm-position measurement fulfilling both validation criteria of the ANSI/AAMI/ISO81060-2:2013 guidelines.

Validation of two watch-type wearable blood pressure monitors according to the ANSI/AAMI/ISO81060-2:2013 guidelines: Omron HEM-6410T-ZM and HEM-6410T-ZL

Mitsuo Kuwabara PhD, Kanako Harada MPH, Yukiko Hishiki BA, Kazuomi Kario MD, PhD

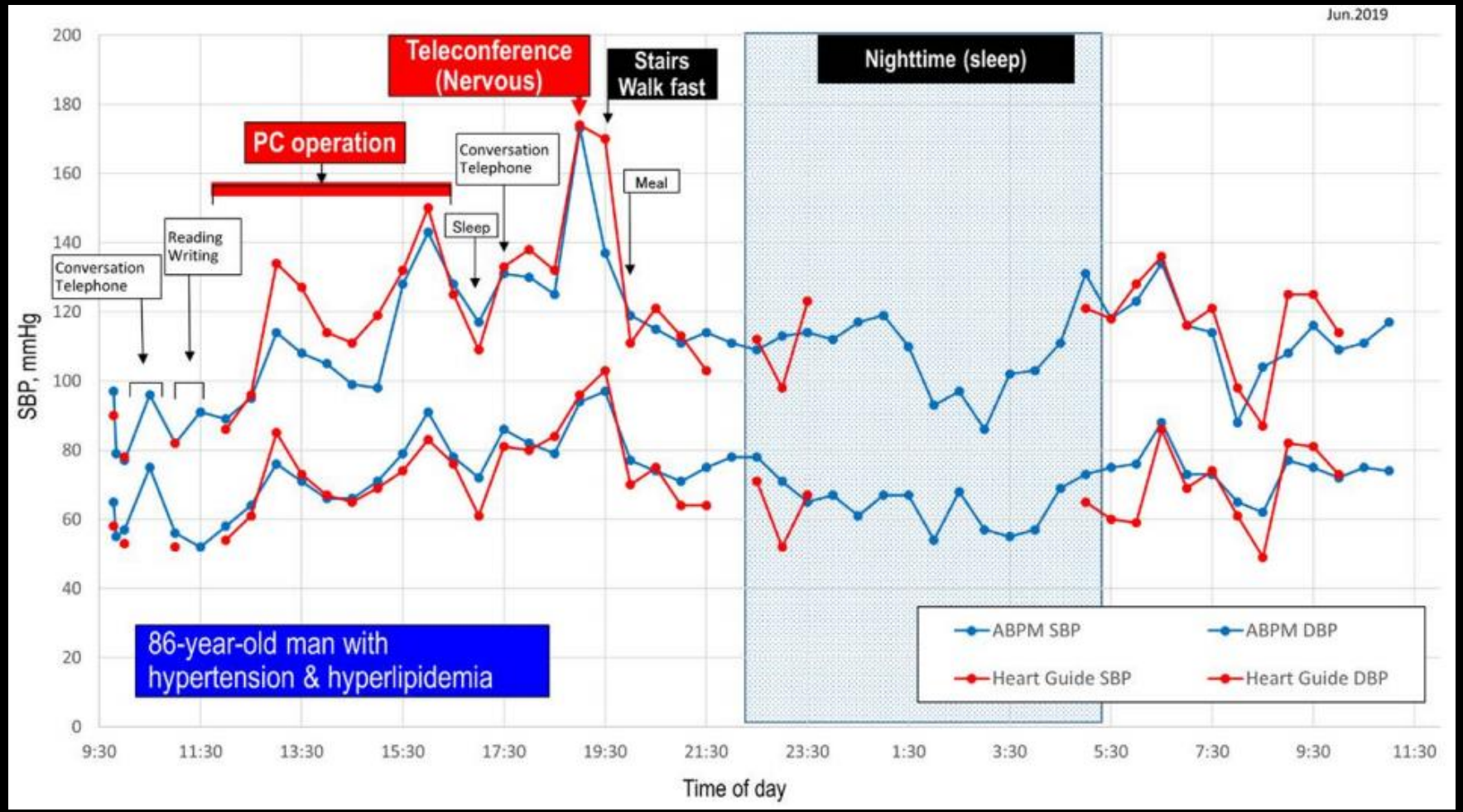
J Clin Hypertens (Greenwich). 2019 Jun;21(6):853-858

	Validation for HEM-6410T-ZM	Validation for HEM-6410T-ZL
Difference of SBP for criterion 1, mm Hg	−0.9 ± 7.6 (passed)	2.4 ± 7.3 (passed)
Difference of SBP for criterion 2, mm Hg	−0.9 ± 6.8 (passed)	2.4 ± 6.46 (passed)
Difference of DBP for criterion 1, mm Hg	−1.1 ± 6.1 (passed)	0.7 ± 7.0 (passed)
Difference of DBP for criterion 2, mm Hg	−1.1 ± 5.5 (passed)	0.7 ± 6.5 (passed)



The watch-type BP monitor has the limitation that patients must set their wrist at their heart level for a precise reading. Some

Comparison of simultaneous monitoring with a wearable device and ABPM



Kario K. Hypertension. 2020 Sep;76(3):640-650

Problems of the cuff-based BP measurement

- ✗ Intermittent rather than continuous measurements
- ✗ Unable to evaluate very-short-term BP variability
- ✗ Only in static conditions
- ✗ Effect of cuff inflation and vascular occlusion

Wearable BP devices

- Non-invasive and cuffless measurements
- BP record comfortably
- Multiple or even continuous, rather than a small sample of measurements
- Unaffected by body position and movements?
- Detailed and unbiased information regarding circadian BP patterns and variability?
- Complete picture of BP profile?

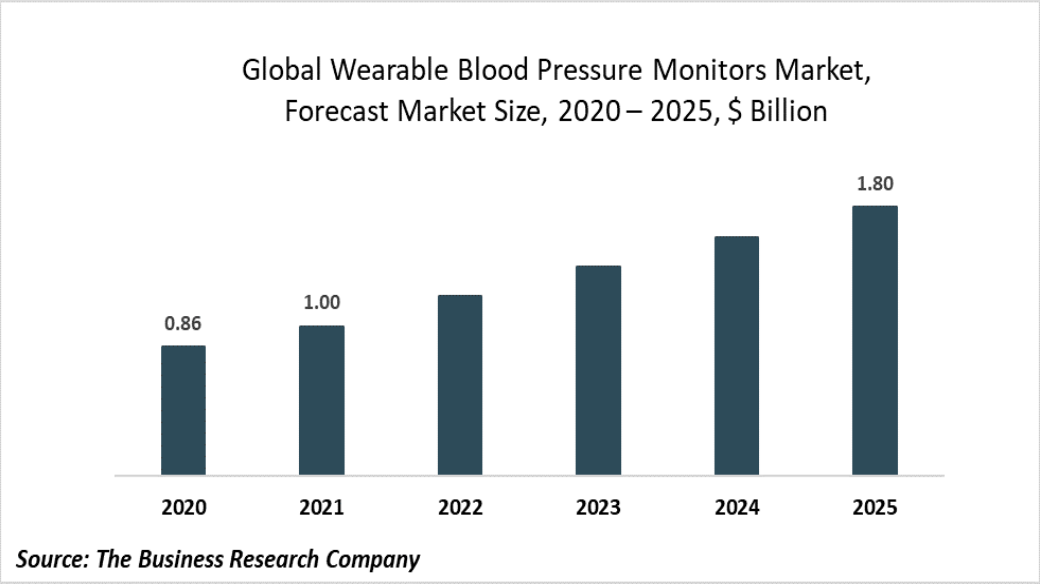
Wearable cuffless BP devices: Can they improve HTN awareness and management?

- Reliable measurements?
- Schedule? Thresholds?
- Type of intervention?

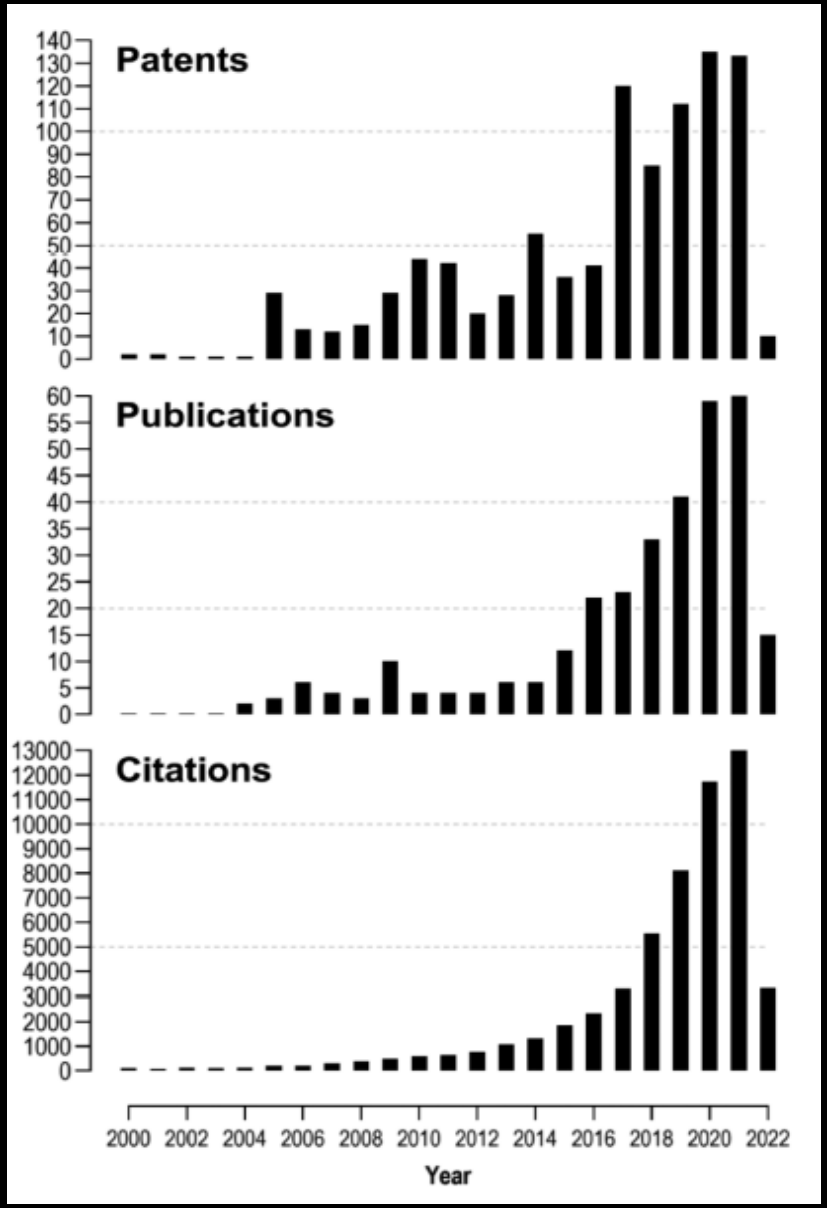
Wearable in clinical practice…

- In order to recommend something for clinical use, it has to be able to provide reliable information on which to base patient decisions.
- For something new to be useful in medicine, it need only do something a little bit better by certain criteria — maybe patients prefer it, maybe it improves outcome — but we need it to show some benefit on top of what we have.
- We don't just add new things because they provide information. We have to prove that the information is reliable and can improve how we provide care.

The economic and scientific burden



Many cuffless devices are already available but this is being driven primarily by financial rather than scientific interest



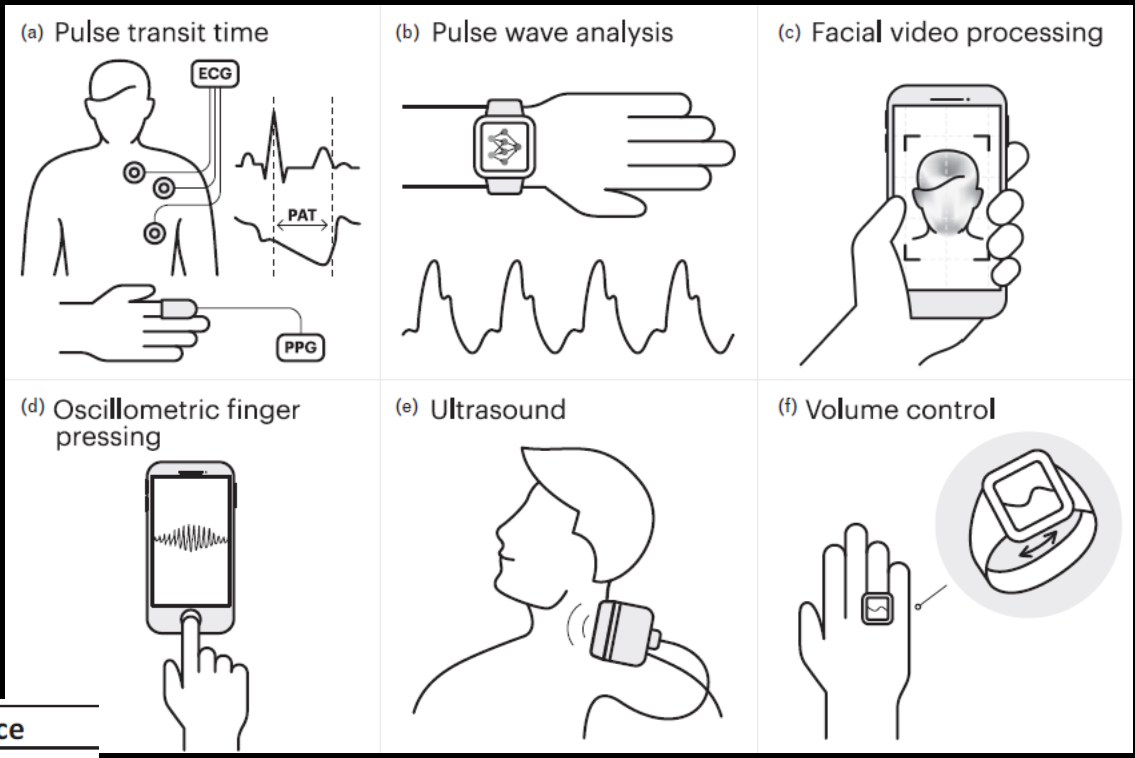
Several factors influence the rising popularity of wearable devices, including comfort, the growing adoption of mobile platforms and preference towards home-based healthcare

Stergiou GS, et al. J Hypertens. 2022 Aug 1;40(8):1449-1460

Cuffless BP technologies

Consensus Document

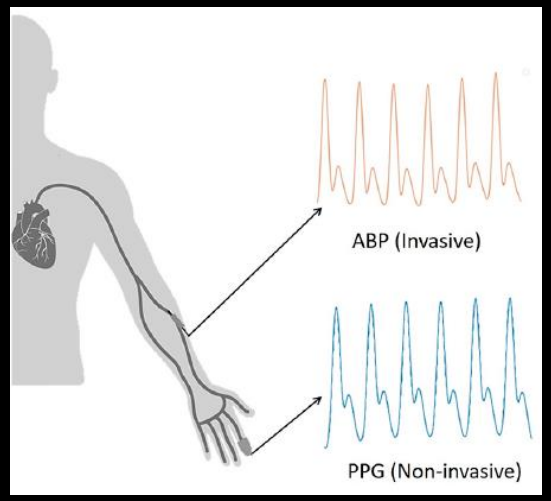
Cuffless blood pressure measuring devices: review and statement by the European Society of Hypertension Working Group on Blood Pressure Monitoring and Cardiovascular Variability

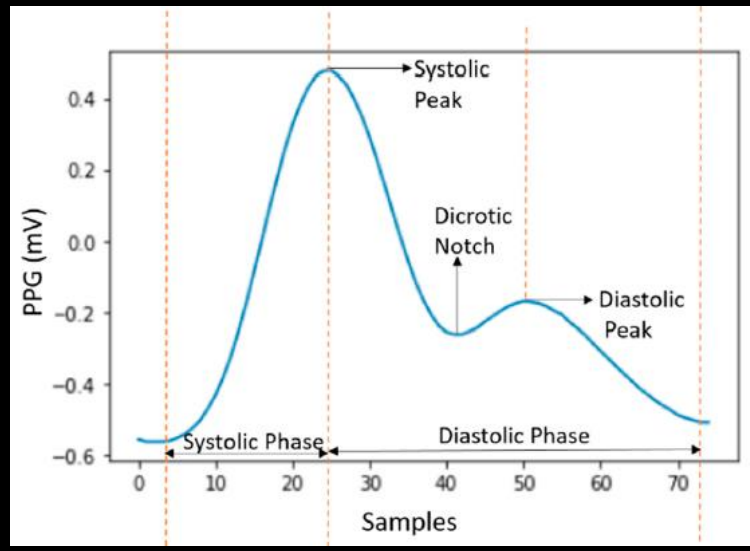


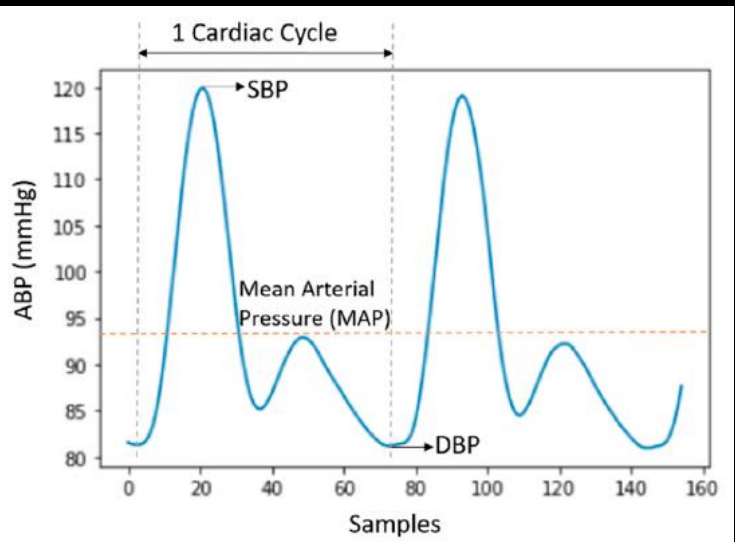
Category	Method	Advantages		Disadvantages		Evidence
Requiring user cuff calibration (*Estimate BP changes*)	PTT (a)	Continuous; without user action; not disturbing	Supporting theory	Calibration via periodic cuff BP measurement or by demographic data input	Two measurements sites	Many published studies
	PWA (b)		Single sensor		Little theory (may not work well in many individuals)	Regulatory-approved, cuff-calibrated, contact monitors
	Facial video processing (c)		Widely available device (smartphone)		Insufficient waveform Quality	Little published data on intra-individual BP change tracking
Not requiring user cuff calibration (*Estimate BP values*)	Oscillometric finger pressing (d)	Calibration not needed; solid theory (could work in many individuals)	Potential widely available device (smartphone)	User action		Few published studies
	Ultrasound (e)		Central PP measurement	Difficult probe placement (operator required)		
	Volume control (f)		Continuous	Disturbing (finger numbness)		

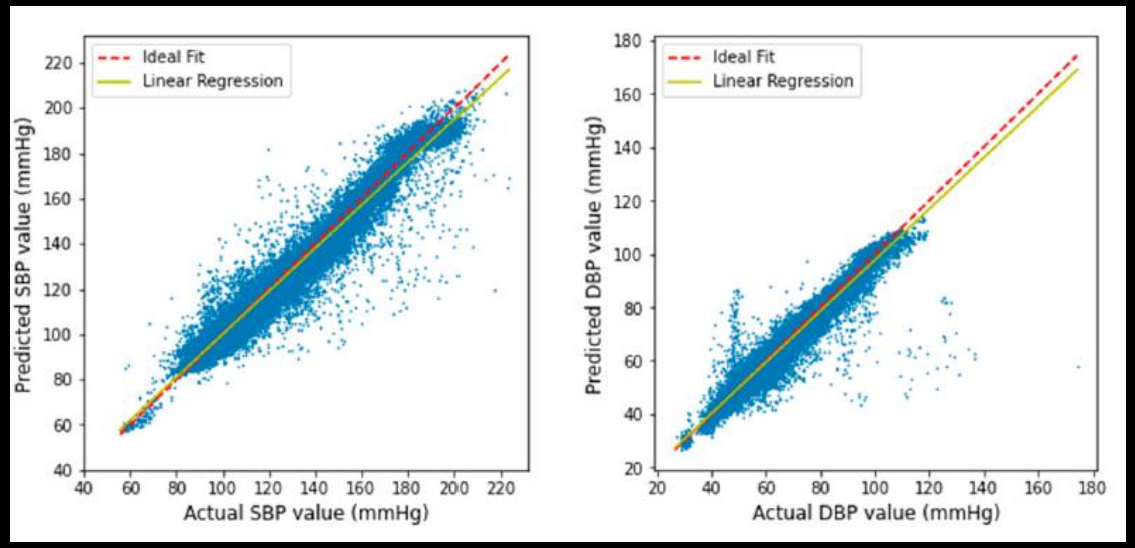
Stergiou GS, et al. J Hypertens. 2022 Aug 1;40(8):1449-1460

Photoplethysmography





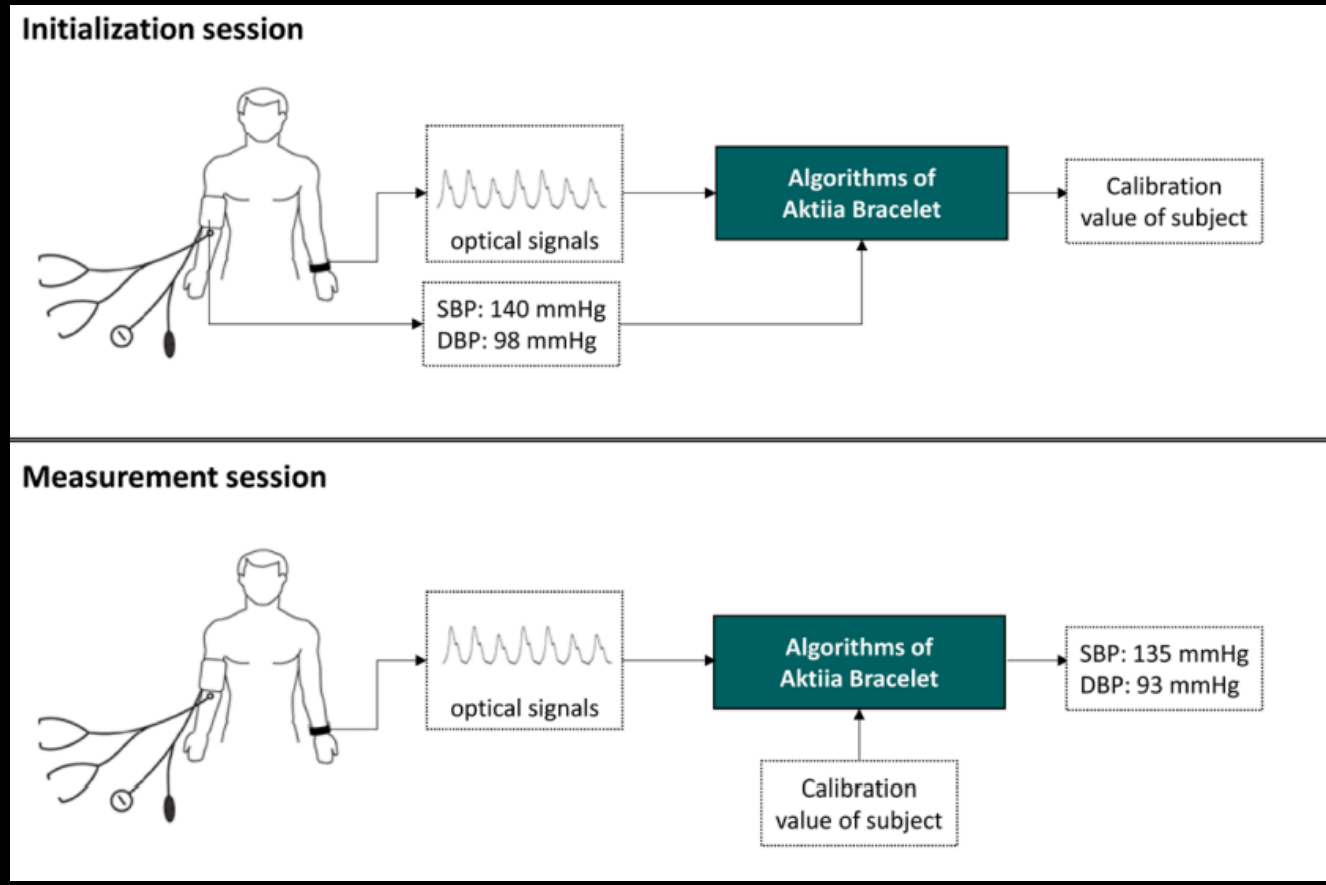




Athaya T, et al. Sensors (Basel). 2021 Mar 7;21(5):1867

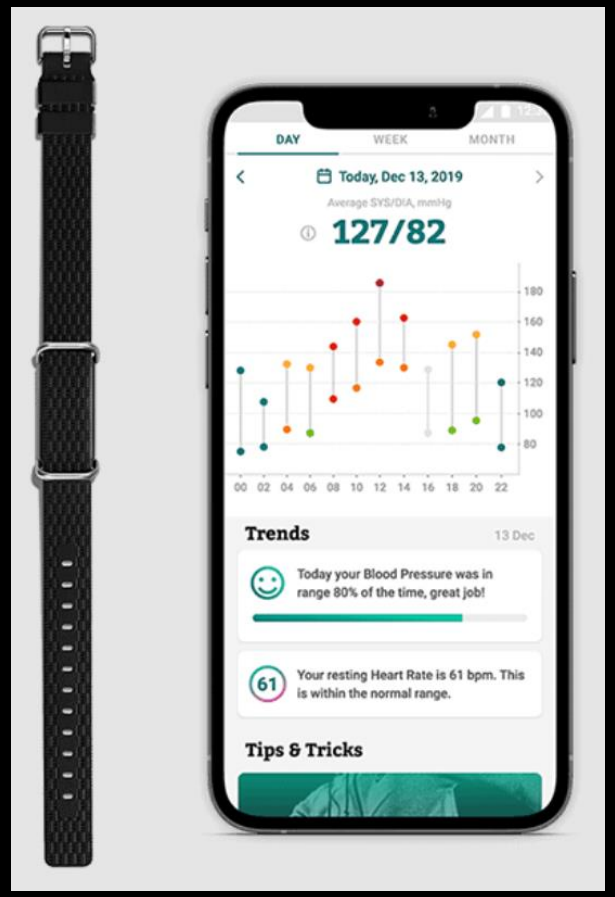
They predict changes of BP

- Need to be calibrated
- Calibration usually performed using a validated automated oscillometric upper arm cuff device
- Often employ a mathematical model that combines demographics with a cuffless measurement from the individual as inputs to ‘predict’ BP



Vybornova A, et al. Blood Press Monit. 2021 Mar 4

Aktiia 24/7



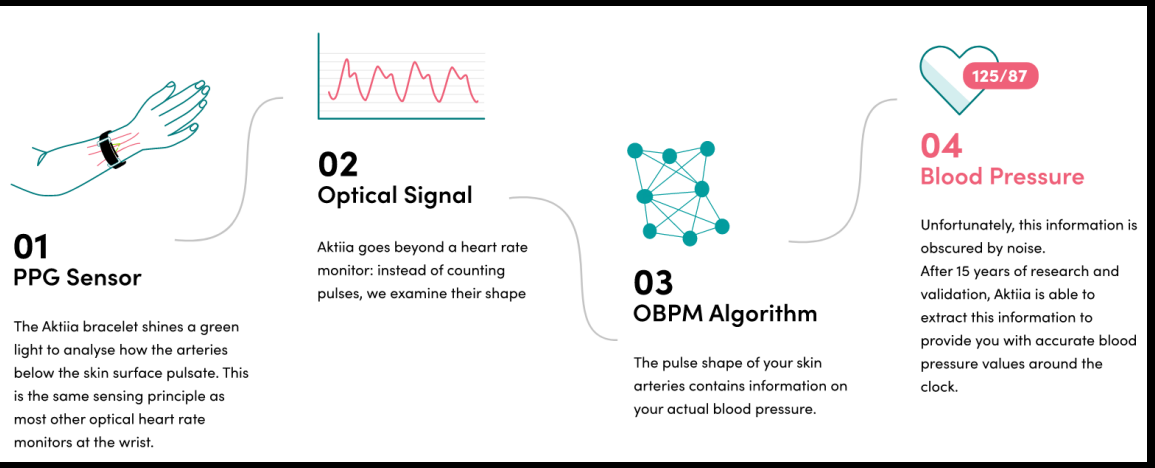


Table 2 Mean and SD of the differences between reference and the Aktiia Bracelet

	Criterion 1[a]	Criterion 2[b]
Systolic blood pressure (mmHg)	0.46 ± 7.75 mmHg	3.9 mmHg
Diastolic blood pressure (mmHg)	0.39 ± 6.86 mmHg	3.6 mmHg

DBP, diastolic blood pressure; SBP, systolic blood pressure.
[a]Passing if SBP and DBP: ≤5 ± 8 mmHg.
[b]Passing if ≤6.91 mmHg for SBP, and <6.93 for DBP.

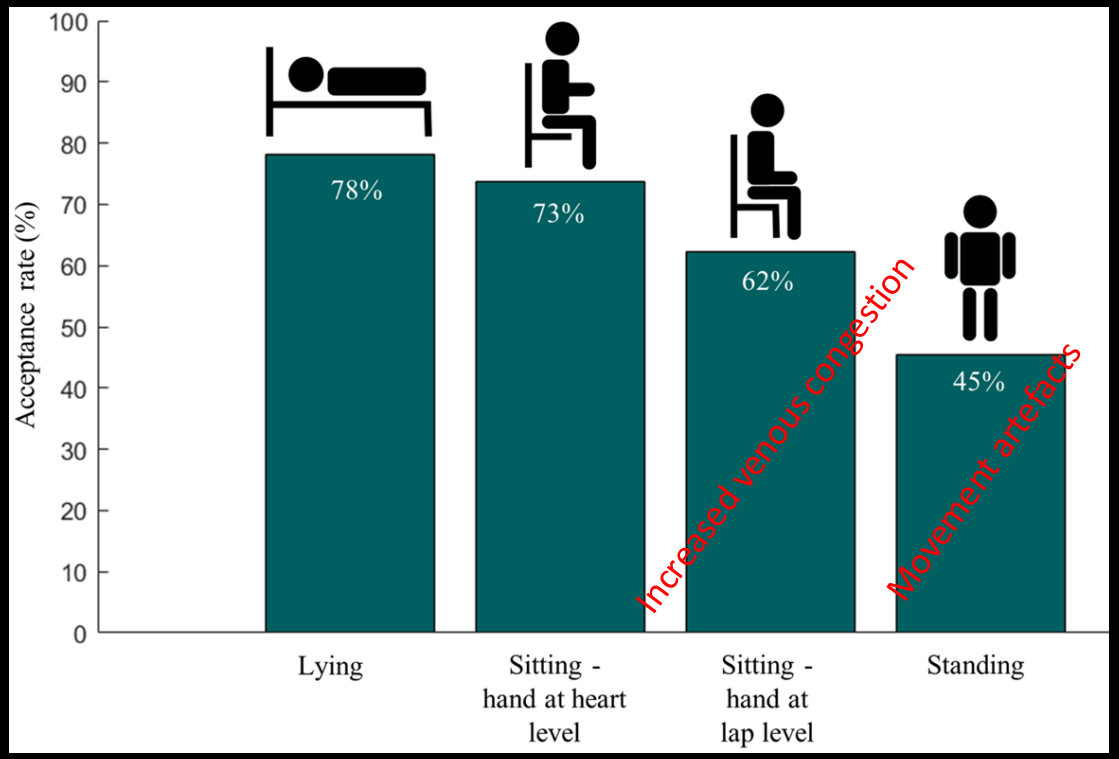
Table 3 Percentage of absolute blood pressure differences between reference and the Aktiia Bracelet within 5, 10 and 15 mmHg

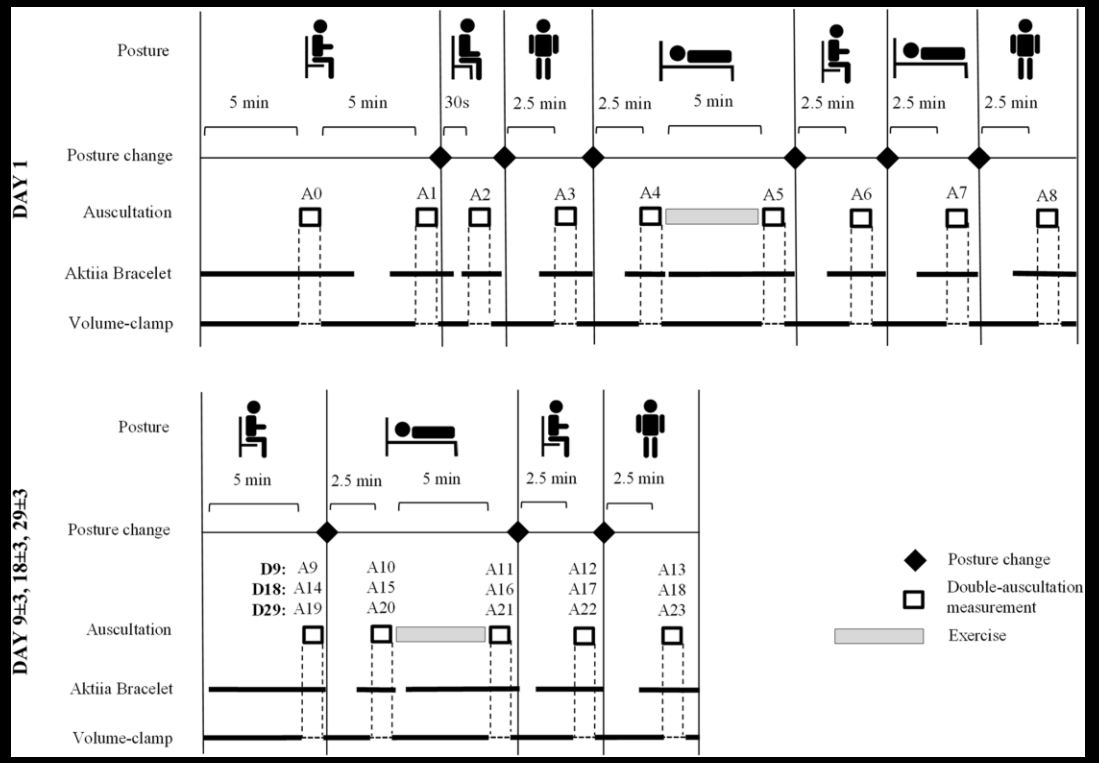
	≤5 mmHg (%)	≤10 mmHg (%)	≤15 mmHg (%)
Systolic blood pressure (mmHg)	58.7	83.2	92.3
Diastolic blood pressure (mmHg)	59.0	83.5	94.5

American National Standard
ANSI/AAMI/ISO 81060-2:2013
AAMI

Vybornova A, et al. Blood Press Monit. 2021 Mar 4

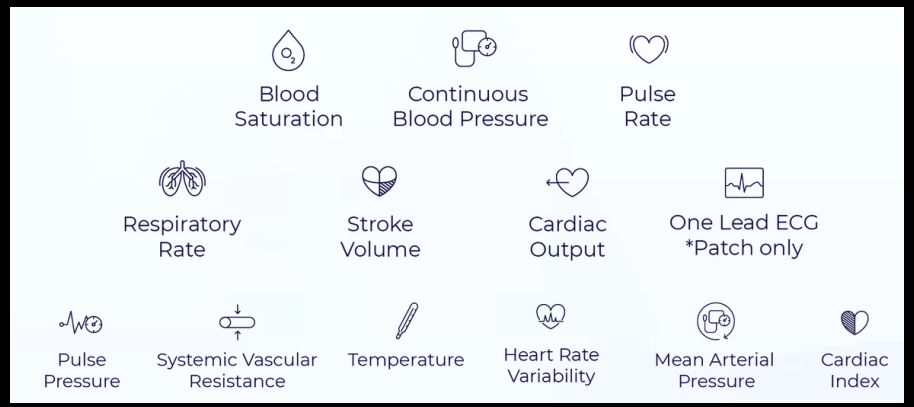
Aktiia in different body positions





	N readings	Systolic blood pressure			Diastolic blood pressure		
		Accuracy	ISO81060-2		Accuracy	ISO81060-2	
		Mean ± Std (mmHg)	Criterion 1	Criterion 2	Mean ± Std (mmHg)	Criterion 1	Criterion 2
Sitting—wrist at heart level	335	0.46 ± 7.75	PASS	PASS	0.39 ± 6.86	PASS	PASS
Sitting—wrist at lap level	177	−3.02 ± 6.10	N/A	N/A	−4.22 ± 6.56	N/A	N/A
Lying	146	−2.44 ± 10.15	N/A	N/A	−1.93 ± 7.65	N/A	N/A
Standing	73	−0.62 ± 12.51	N/A	N/A	−4.85 ± 9.11	N/A	N/A
All positions	731	−1.11 ± 9.85	N/A	N/A	−1.32 ± 7.56	N/A	N/A

Sola J, et al. Sci Rep. 2021 Oct 19;11(1):20644



U.S. FOOD & DRUG ADMINISTRATION

FDA APPROVED

August 22, 2019

Intended Use / Indications for Use:

The BB-613WP is a wrist-worn or skin attached device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate.

The BB-613WP can also track changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO_2 sensor, following a calibration process using oscillometric blood pressure monitor.

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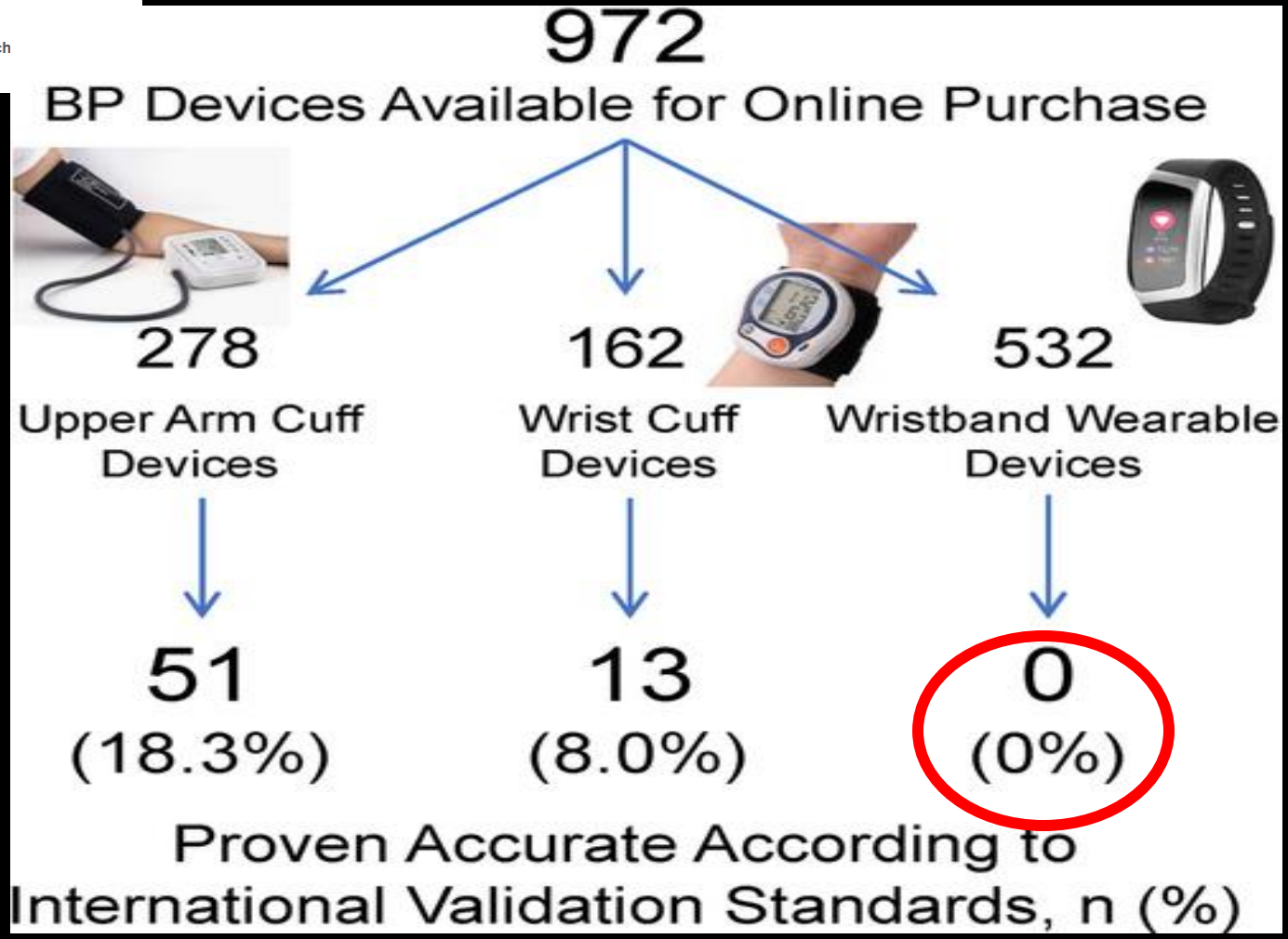
Nonvalidated Home Blood Pressure Devices Dominate the Online Marketplace in Australia

Major Implications for Cardiovascular Risk Management

Dean S. Picone, Rewati A. Deshpande, Martin G. Schultz, Ricardo Fonseca, Norm R.C. Campbell, Christian Delles, Mich
Aletta E. Schutte, George Stergiou, Raj Padwal, Xin-Hua Zhang, James E. Sharman

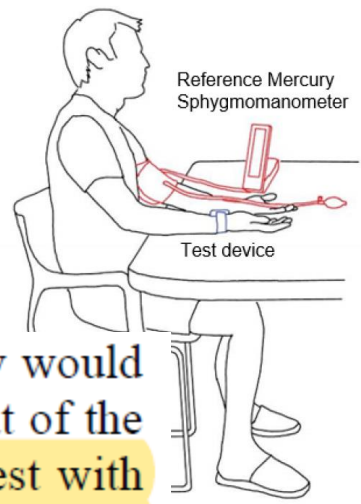


Picone DS, et al. Hypertension. 2020 Jun;75(6):1593-1599

Validation

- When you calibrate a cuffless device, you essentially tell the device your BP measurement, and it uses this as a reference. The cuffless device will pass the universal validation protocol because it repeatedly shows the calibrated BP…
- A cuffless device must prove that it can track BP changes using an established protocol — this is the most important as well as the trickiest part of evaluating cuffless BP devices.
- There are two types of tests we need to assess any kind of technology: lab tests and clinical field tests. You may have a device that is accurate under sterilized research conditions, but I also need a clinical field test to see whether it works for my needs.

Validation
IEEE Standard for Wearable, Cuffless BP Measuring Devices



Concerning the special feature of the cuffless BP measuring devices, where the calibration efficacy would greatly influence the device accuracy, the validation procedures are considerably different from that of the cuff-based devices. For each subject, the procedure is broken down into three levels:[1] static test,[2] test with BP change from the calibration point, and[3] test after a certain period of time from calibration. Practitioners should properly design their validation protocol to cover the validation from each of the three levels.

Posture of subject during validation test

Posture of test subjects largely affect the level and accuracy of BP measurements and thus become a crucial factor for device validation test. In this version, the standard provides the test procedure only based on the static condition (see 4.2.2). This standard does not provide recommendations or test methods for performance evaluation of wearable cuffless BP measurement devices during postures other than sitting. If a manufacturer intends for their device to be used in postures other than sitting, the performance during those postures may need to be evaluated in addition to the requirements in this standard. Although the cuffless BP monitoring devices may provide measurements in dynamic conditions such as working and exercises, there is currently no recognized method for stable and accurate measurements for reference devices (cuffed BP monitors) in the dynamic conditions. Therefore, the dynamic test conditions will be covered in a later version of standard.

Wearable Cuffless BP Monitors Working Group: IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices—Amendment 1, New York, IEEE, 2019

Consensus Document

2021 European Society of Hypertension practice guidelines for office and out-of-office blood pressure measurement

SECTION 8: CUFFLESS WEARABLE BP MONITORS [18]

A large number of cuffless wearable (wrist-band) devices are available on the market claiming that they accurately measure BP. These devices have a sensor, which evaluates the pulsation of arterioles and estimate BP based on pulse wave velocity, or other technologies. Cuffless wearable devices have great potential as they can obtain multiple or even continuous BP measurements for days or weeks without the disturbance of cuff-induced limb compression. The assessment of the accuracy of cuffless devices requires the use of a validation protocol, which is specific for these devices and includes procedures additional to those used for conventional cuff-devices. At present, the accuracy and usefulness of cuffless devices are uncertain. Therefore, they should not be used for diagnostic or treatment decisions.

Recommendation for Cuffless BP Devices

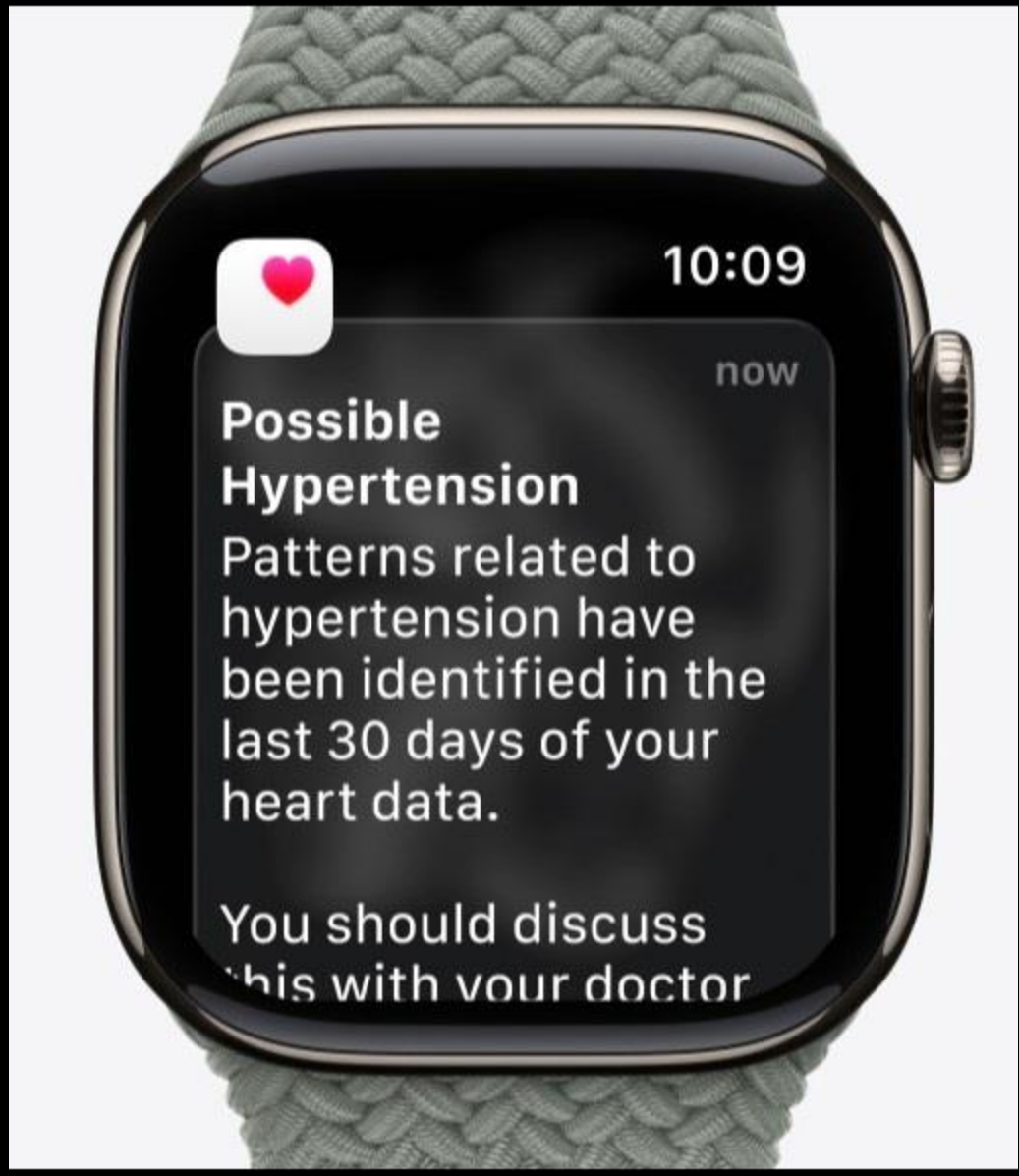
COR	LOE	RECOMMENDATION
3: No Benefit	C-LD	1. In adults, the use of cuffless BP devices is not recommended for the diagnosis or management of high BP.[1-3]

ACC/AHA 2025

Stergiou GS, et al. J Hypertens. 2021 Mar 11

The Apple Watch

- The Apple Watch (Series 9/10/11, Ultra 2/3) features a hypertension notification system with a sensitivity of 41.2% and a specificity of 92.3%.
- This indicates a low sensitivity, meaning it may miss about 60% of cases, while the high specificity results in few false alarms.
- It is designed for screening, not diagnosis.



Prognostic value?

- It might take 20 years of research to know what a new measurement meant in terms of clinical outcomes

- We had been working with the auscultatory method for many years, when oscillometry appeared. The developers realized that in order to be successful, they had to replicate the numbers that auscultation gives

Perspectives

- A 24/7 BP device would be an excellent candidate to not only provide an alternative to HBPM/ABPM in terms of cost-efficiency and patient adherence but also to extend existing use-cases by providing insights into individual daily, monthly and yearly BP rhythms.

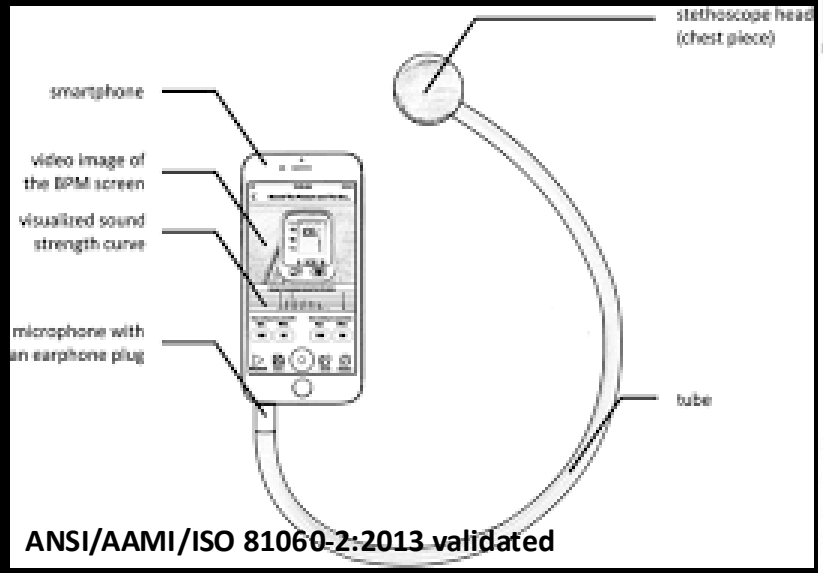
- This would enable the first-ever large-scale phenotyping of populations in addition to driving personalized approaches for the diagnosis and the management of HTN.

Conclusion

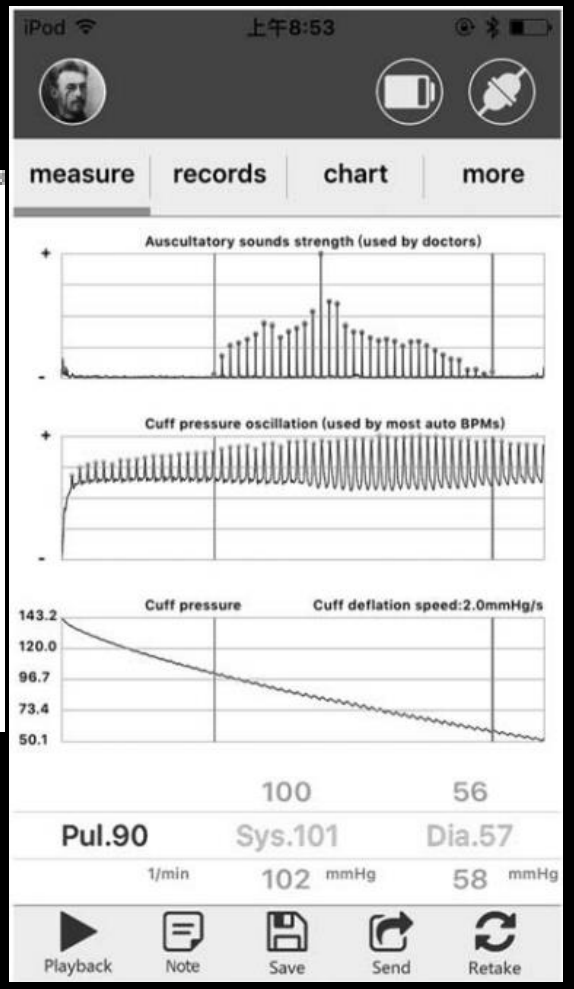
- We are at a momentum of change in healthcare due to
  - Improvement of informatics performance and algorithm effectiveness
  - Better acceptation from patients and professionals
  - Interest of regulatory authorities
  - Change from randomized to real life studies
  - Change of payment modalities (from pay for therapy / pay for effective service)
  - Need of distancing due to COVID
- The question of reorganization of healthcare is crucial.
- Digitalization should not be defined only by it’s medical dimension but with a 360^{o} approach (patient/pathways/costs/datascience/effectiveness).
- Digitalization is mandatory but has to be support by national authorities.

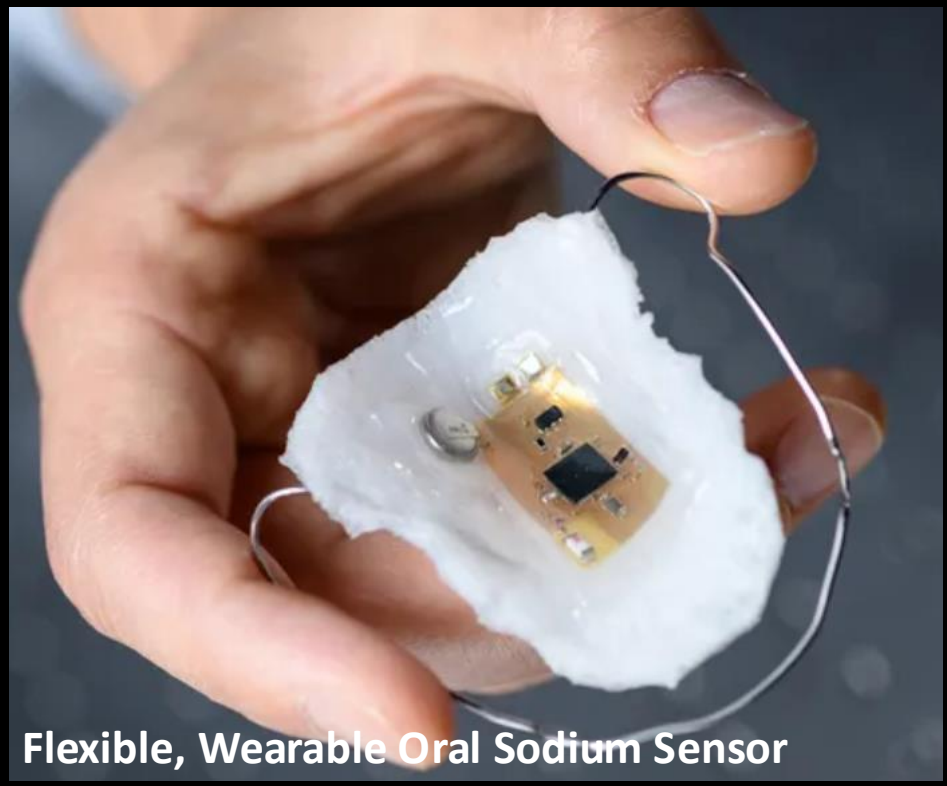
There is no limit…

A smartphone auscultatory BP kit



ANSI/AAMI/ISO 81060-2:2013 validated





Chu G, et al. Blood Press Monit. 2017 Oct;22(5):290-294

Future

- OBP
- ABPM
- Attended
- Unattended
- ***TBP***
- ***WBP***

Big data refers to the enormous amount of structured as well as unstructured data, which helps organizations to improve their decision making processes.

Technology is not the panacea for the healthcare industry... but it is part of the solution!