Traditional and Unconventional Blood Pressure Measurement: **New Approaches Making Waves**

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- Dr. Jordy Cohen has no financial conflicts of interest to disclose relevant to this activity.
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- **Off-Label Use:** My presentation does not include discussion of off-label or investigational use of drugs. Several blood pressure measurement devices (finger and cuffless devices) that are not FDA approved are described, specifically to make providers aware that these are not valid devices and are not recommended for clinical use.

Learning Objectives

- Discuss the current practices in blood pressure measurement
- Identify the importance of accurate blood pressure measurement
- Discuss ways of optimizing in-office blood pressure measurement
- Give examples of implementation of out-of-office blood pressure measurement in clinical practice
- Provide additional tools for optimizing measurement quality
- Suggest future directions of blood pressure measurement

- “The greatest danger to a man with high blood pressure lies in its discovery, because then some fool is certain to try and reduce it”
    - John H. Hay. *Br Med J* 1931; 2(3679): 43–47

The first direct measurement of blood pressure

- “Since animal fluids move by hydraulic and hydrostatic laws, the likeliest ways therefore to succeed in our inquiries into the nature of their motions, is by adapting our experiments to those laws”
  - Rev. Stephen Hales, 1710

The first non-invasive blood pressure measurement

- In 1896, Scipione Riva Rocci introduced the sphygmomanometer to facilitate measurement of blood pressure in the clinic
  - Built using an inkwell, some copper pipe, bicycle inner tubing and *mercury*

Evolution of blood pressure measurement: Understanding its clinical importance

- Over the next century, mercury was responsible for assuring uniformity of BP measurement in the first studies to identify the risks of elevated BP with regard to cardiovascular outcomes

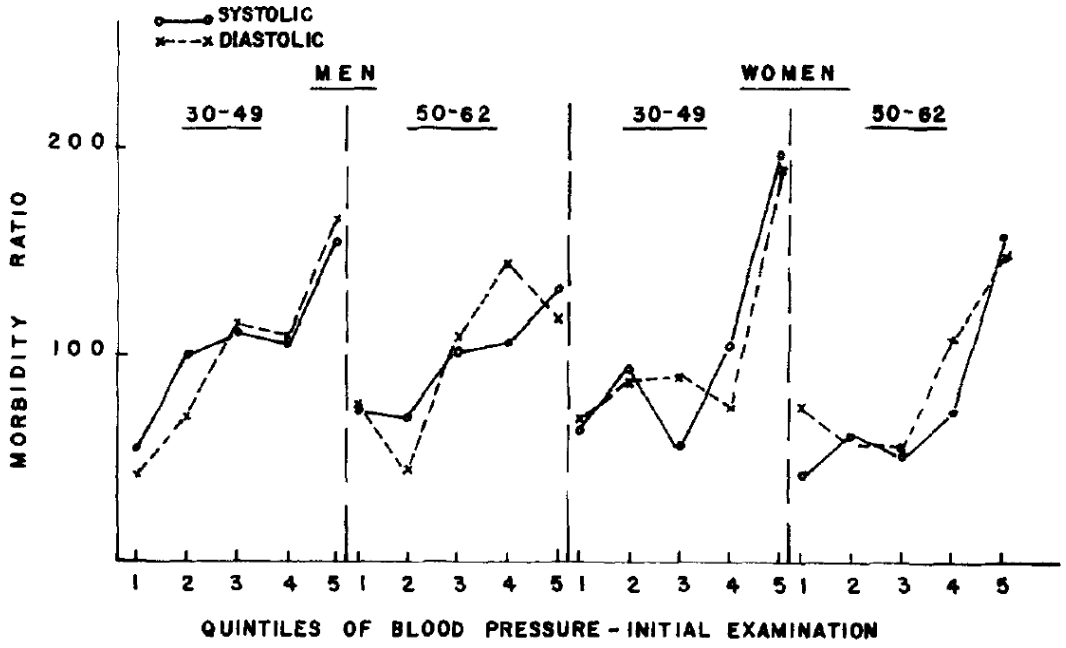
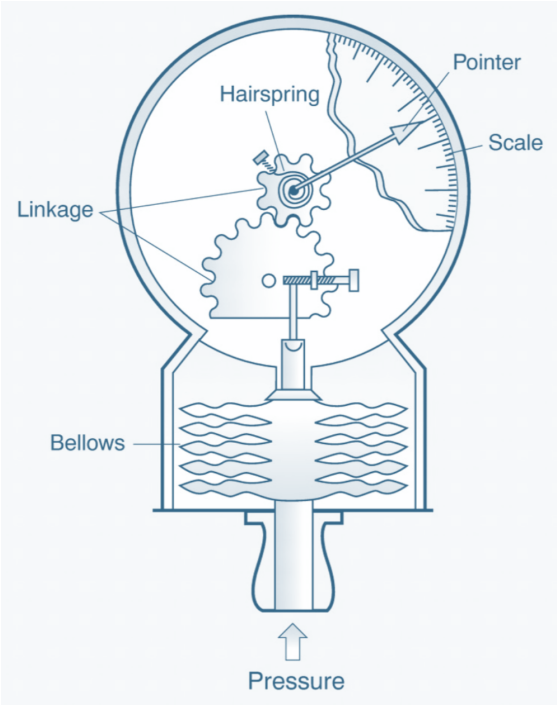


Figure 4. Risk of coronary heart disease (14 year follow-up) according to systolic and diastolic blood pressure. (Men and women aged 30 to 62 years at entry: Framingham study.)

Kannel WB et al. *Am J Cardiol*. 1971 Apr;27(4):335-46

Evolution of blood pressure measurement: Mercury to aneroid

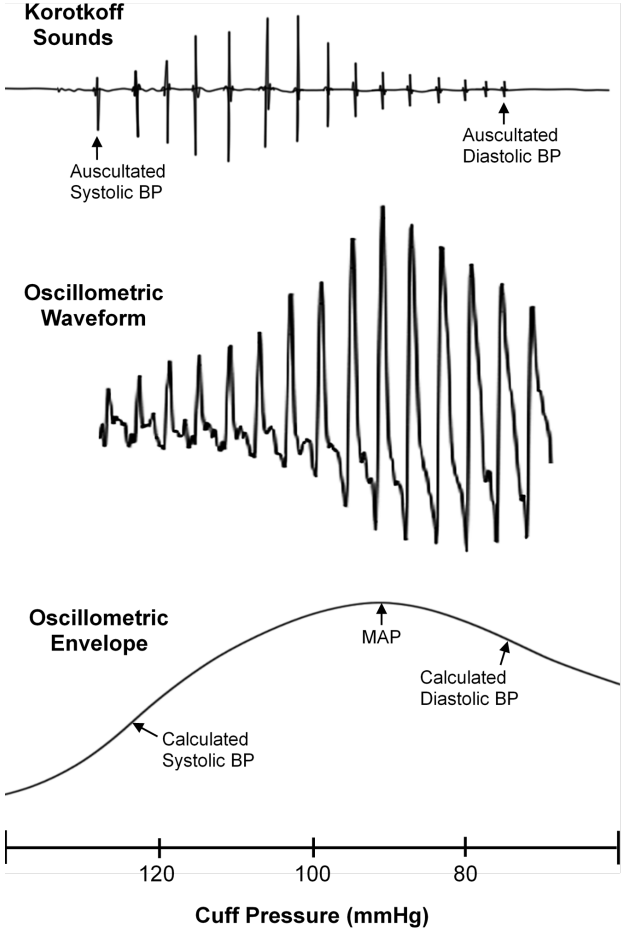
- In 2013-2014, international hypertension societies concluded that the risk of mercury toxicity superseded any potential benefit
- Transition to aneroid measurement
  - Benefits: Inexpensive, readily accessible
  - Limitations: **Require frequent calibration**, continued element of human error (e.g. digit bias)



Cohen JB et al. *Hypertension* 2019; 73:258-264

Evolution of blood pressure measurement: Aneroid to oscillometric

- Transition to oscillometric measurement
  - In-office: standard oscillometric monitor, single blood pressure measurement
  - Benefits: Reduce human error
  - Limitations: Continued element of measurement error, **require validation**



Cohen JB et al. *Hypertension* 2019; 73:258-264

Evolution of blood pressure measurement: The modern provider's office

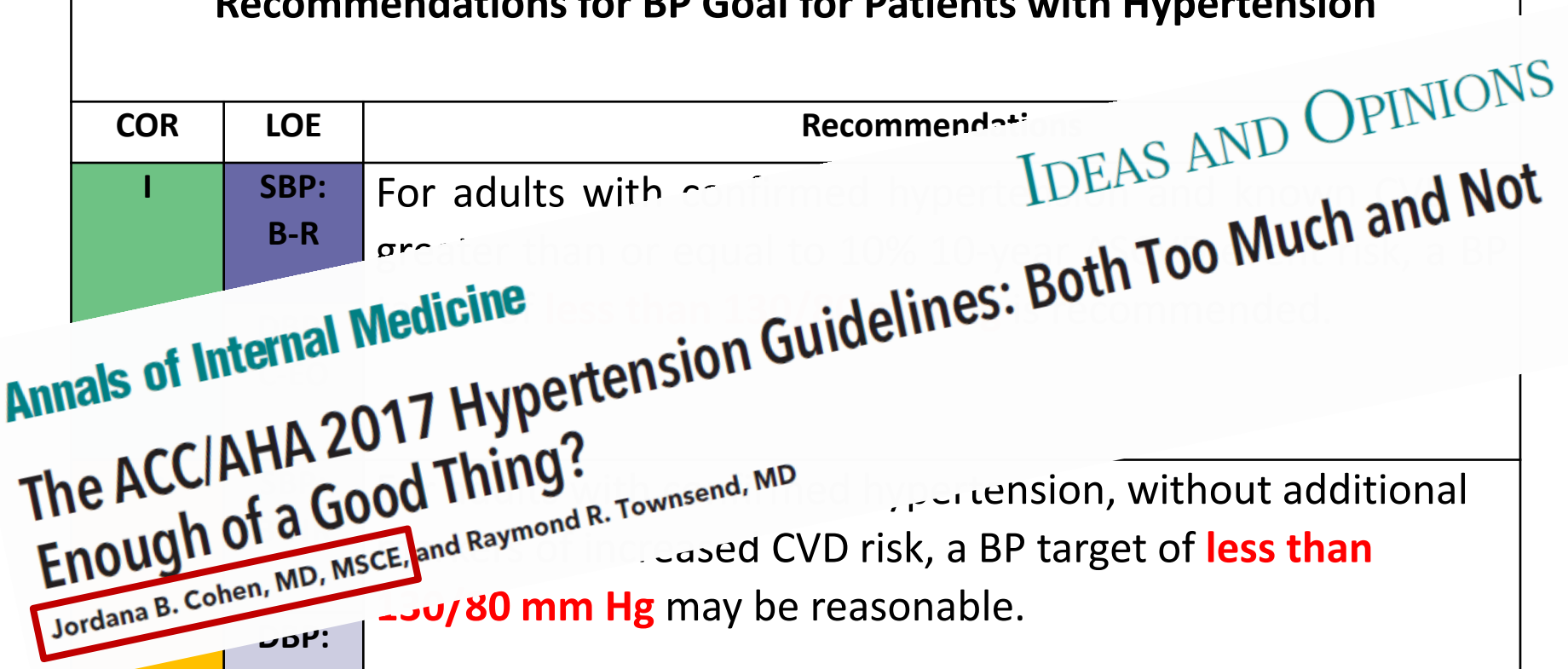
- More sophisticated studies continually provide more detailed information the clinical importance of achieving increasing *precise blood pressure goals*
- We do not always have time or support to perform the highest quality readings
- Reimbursement is tied to in-office blood pressures

Carey RM et al. *Hypertension* 2018; 72(5)

ACC/AHA 2017 Guideline for the Prevention, Detection, Evaluation of High Blood Pressure in Adults

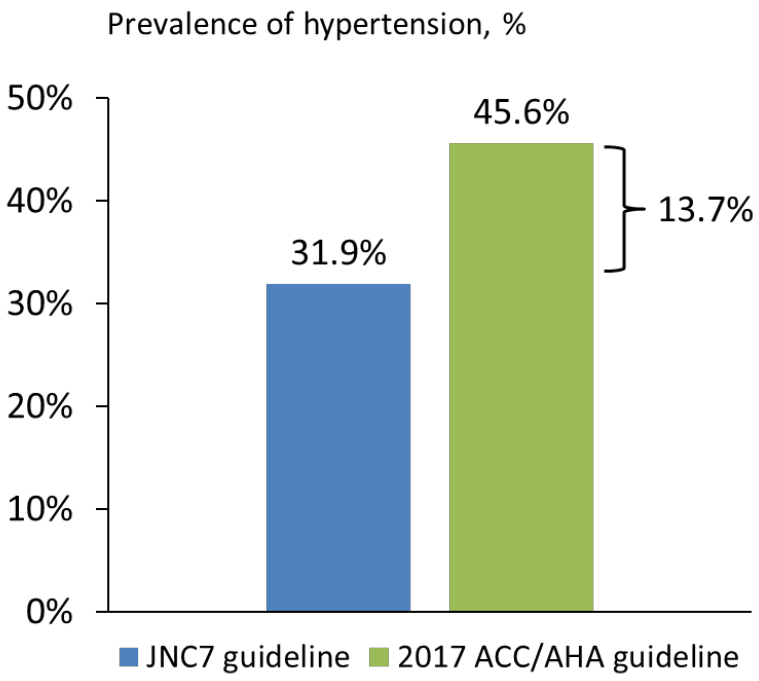
Recommendations for BP Goal for Patients with Hypertension

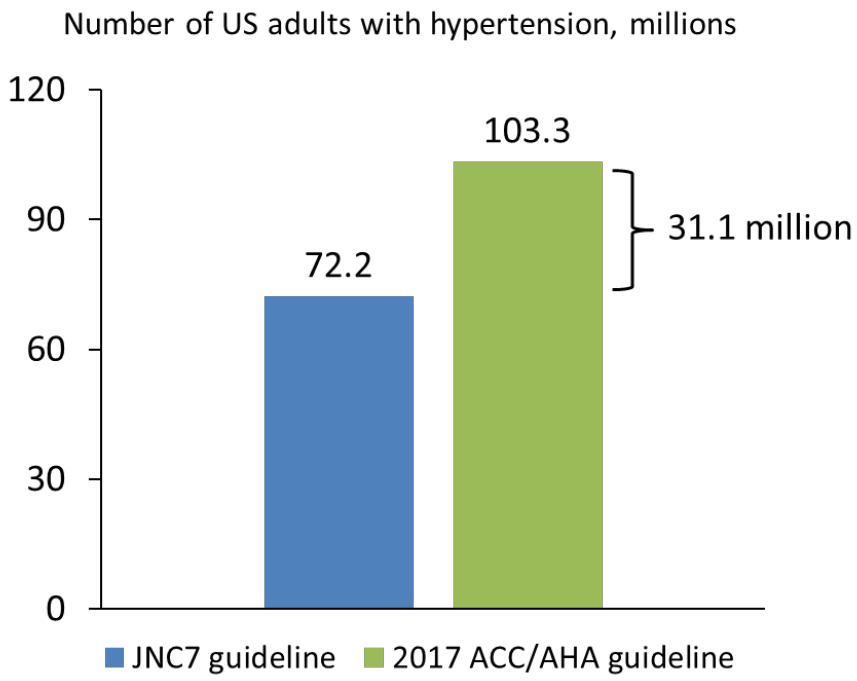
COR	LOE	Recommendations
I	SBP: B-R	For adults with confirmed hypertension and known CVD or 10-year CVD risk greater than or equal to 10%, treatment to a BP less than 130/80 mm Hg is recommended.
	SBP: C-EO	For adults with confirmed hypertension, without additional clinical CVD or increased CVD risk, a BP target of **less than 130/80 mm Hg** may be reasonable.



Whelton PK et al. *J Am Coll Cardiol* 2018; 71(19)

The enormous potential impact of the new definition for hypertension





Muntner P et al. *Circulation* 2018; 137(2)

The guideline stresses (and assumes) optimal blood pressure measurement

COR	LOE	Recommendation for Accurate Measurement of BP in the Office
I	C-EO	For diagnosis and management of high BP, proper methods are recommended for **accurate measurement and documentation of BP**.

Whelton PK et al. *J Am Coll Cardiol* 2018; 71(19)

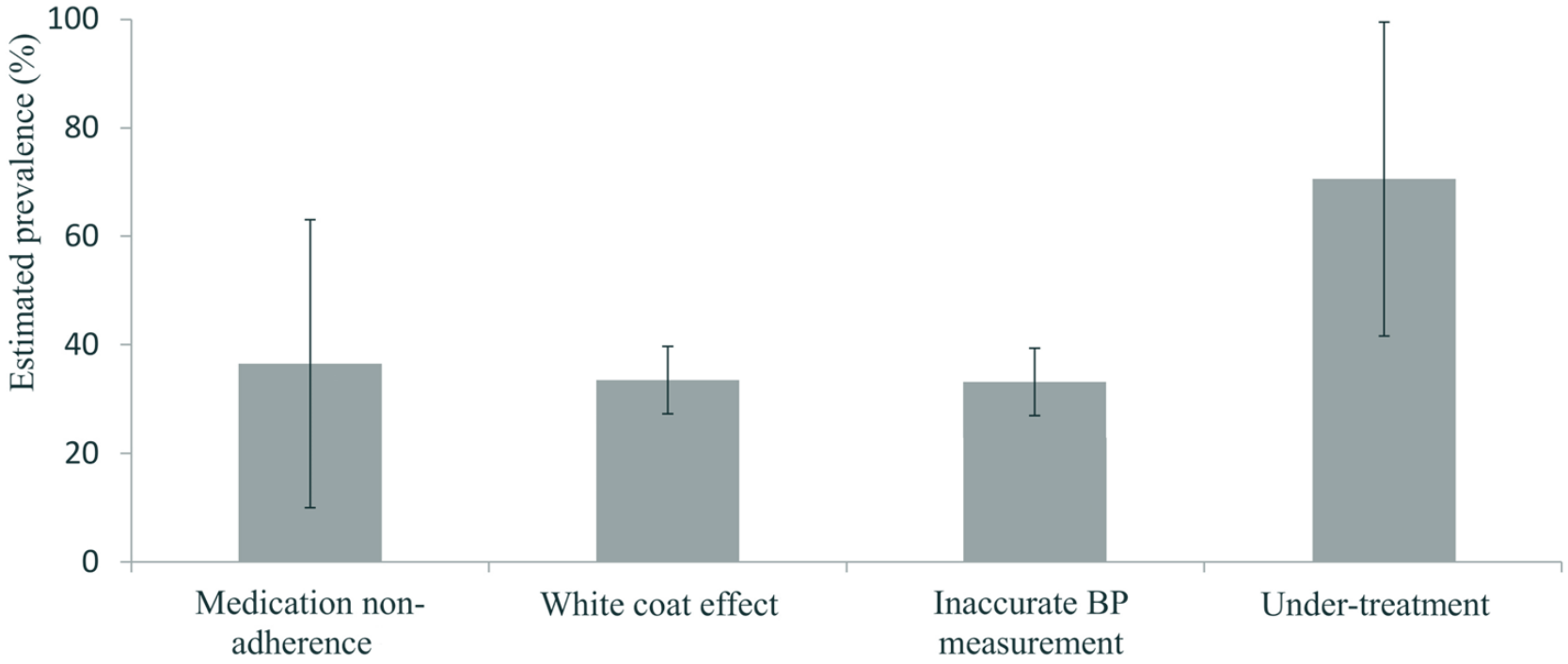
Differences in clinic vs. research study BP measurements

Study	Number of patients	Routine clinic BP	Research study BP	Delta BP
Myers et al. 1995	147	146/87	140/83	6/4
Brown et al. 2001	611	161/95	152/85	9/10
Graves et al. 2003	104	152/84	138/74	14/10
Gustavsen et al. 2003	420	165/104	156/100	9/4
Myers et al. 2009	309	152/87	140/80	12/7
Head et al. 2010	6817	150/89	142/82	12/7
Burgess et al. 2011	150	145/85	132/79	7/6
Overall	**8558**	**153/90**	**143/83**	**10/7**

Myers MG. *J Hypertens* 2012;30

Evolution of blood pressure measurement: Missed opportunities

- High prevalence of pseudo-resistant hypertension, resulting in misclassification and over-prescribing of antihypertensives



Carey RM et al. *Hypertension* 2018; 72(5)

The great myth of office blood pressure measurement

Martin G. Myers[b]

Office Blood Pressure Measurement
The Weak Cornerstone of Hypertension Diagnosis

George Stergiou, Anastasios Kollias, Gianfranco P[illegible], Eoin O'Brien

Blood pressure measurements are unreliable to diagnose hypertension in primary care

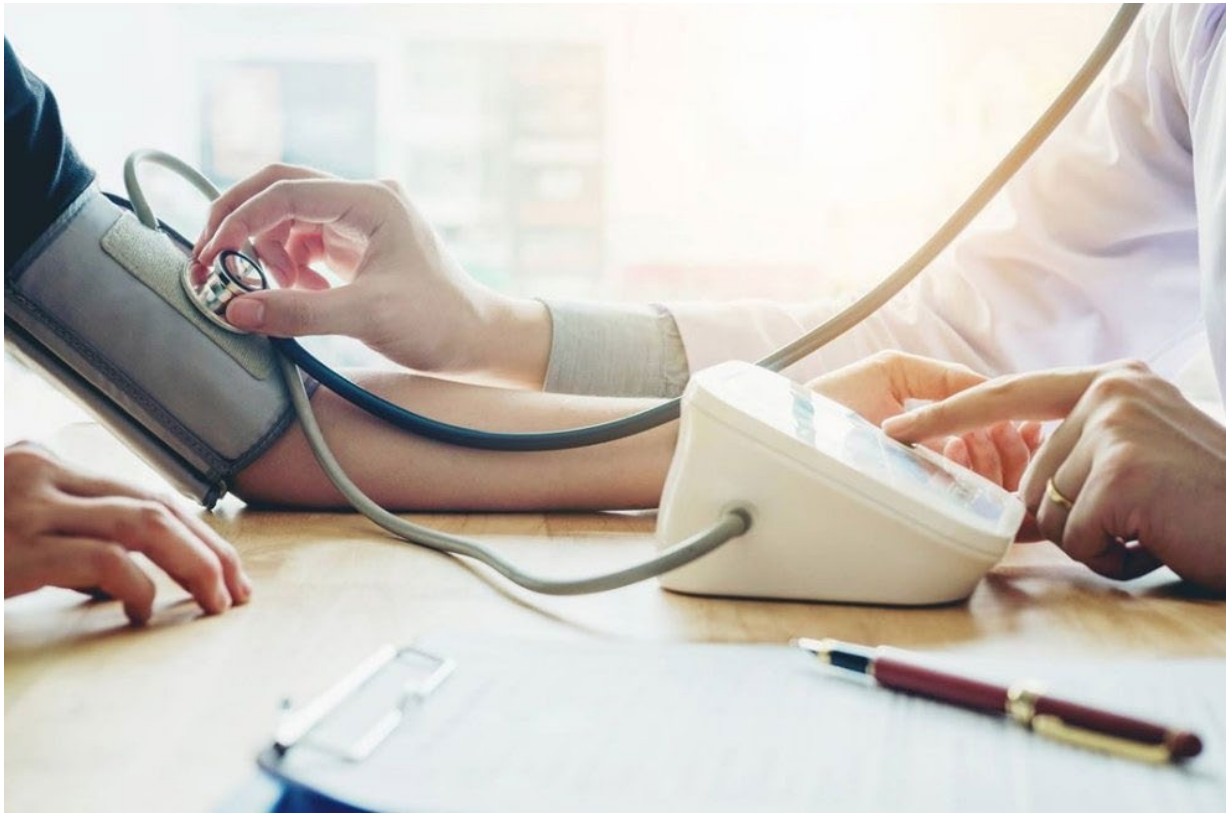
Paul Sebo[a], Antoinette Pechère-Bertschi[b,c], François R. Herrmann[d], Dagmar M. Haller[a,b,e], and Patrick Bovier[f]

Physicians are only human…

- American Medical Association Blood Pressure Check Challenge

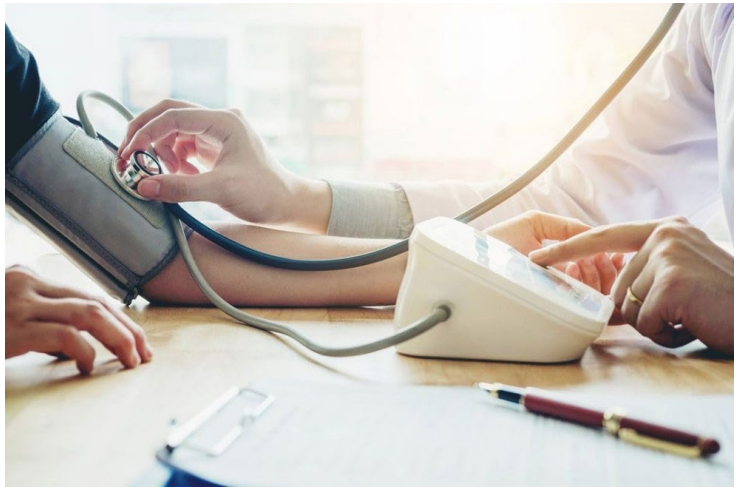
	All (n=159)
Rest 5 min in chair prior to measurement, %	6.9
Legs uncrossed, %	52.2
Feet on floor, %	15.1
Arm supported, %	61.0
Correct cuff size, %	73.6
Cuff over bare arm, %	83.0
No talking, %	57.2
No mobile phone use/reading, %	17.0
Checked in both arms, %	18.2
Noted arm with higher reading, %	15.1
Correctly answered which arm to be used to measure in future, %	13.2
Mean performance score	4.1

Frequent issues with in-office blood pressure measurement



Frequent issues with in-office blood pressure measurement

- Improper technique
  - Lack of 5 minute rest
  - Patient position, cuff size, clothes
  - Noise level
  - Insufficient time for cuff deflation
- Single reading
- Digit bias
- White coat effect
- Masked hypertension



Cohen JB and Townsend RR. *Ann Intern Med* 2018;168(4)

Table 9. Blood Pressure Variability[52]	
Factor	**Systolic (mmHg)**
Cuff too small	10–40 ↑
Cuff over clothing	10–40 ↑ or ↓
Back/feet unsupported	5–15 ↑
Legs crossed	5–8 ↑
Arm tense	15 ↑
Not resting 3 to 5 minutes	10–20 ↑
Anxiety/white coat hypertension	As much as 30 ↑
Patient talking	10–15 ↑
Labored breathing	5–8 ↑
Full bladder	10–15 ↑
Pain	10–30 ↑
Arm below or above heart level	10 ↑ or ↓ For every 1 cm above or below heart level, blood pressure varies by 0.8 mmHg.
Factor	**Diastolic (mmHg)**
Arm extended and unsupported	Diastolic ↑ 10%

7 SIMPLE TIPS TO GET AN ACCURATE BLOOD PRESSURE READING

The common positioning errors can result in inaccurate blood pressure measurement. Figures shown are estimates of how improper positioning can potentially impact blood pressure readings.

Sources:

1. *Pickering, et al.* Recommendations for Blood Pressure Measurement in Humans and Experimental Animals Part 1: Blood Pressure Measurement in Humans. *Circulation*. 2005;111: 697-716.
2. *Handler J.* The importance of accurate blood pressure measurement. *The Permanente Journal*/Summer 2009/Volume 13 No. 3 51

This *7 simple tips to get an accurate blood pressure reading* was adapted with permission of the American Medical Association and The Johns Hopkins University. The original copyrighted content can be found at https://www.ama-assn.org/ama-johns-hopkins-blood-pressure-resources.

Updated December 2016

TARGET:BP™ | American Heart Association. AMA

One solution to issues with in-office blood pressure measurement: **Automated office blood pressure**

Automated office blood pressure

- Oscillometric device
- Records multiple blood pressure readings (observed or unobserved) after a rest period with a single activation
  - Pre-programmed 5-minute rest, then 3 readings at 1-minute intervals
  - Can calculate an average of these readings

Cohen JB and Cohen D. *Curr Cardiol Rep* 2016; 18

Automated office blood pressure

- Benefits
  - Average of three readings (regression to the mean)
  - Consistent with recent clinical trial methods
  - Correlate well to daytime ambulatory blood pressures
  - Reduce human error
  - Can mitigate white coat hypertension/effect

Cohen JB and Cohen D. *Curr Cardiol Rep* 2016; 18

Automated office blood pressure

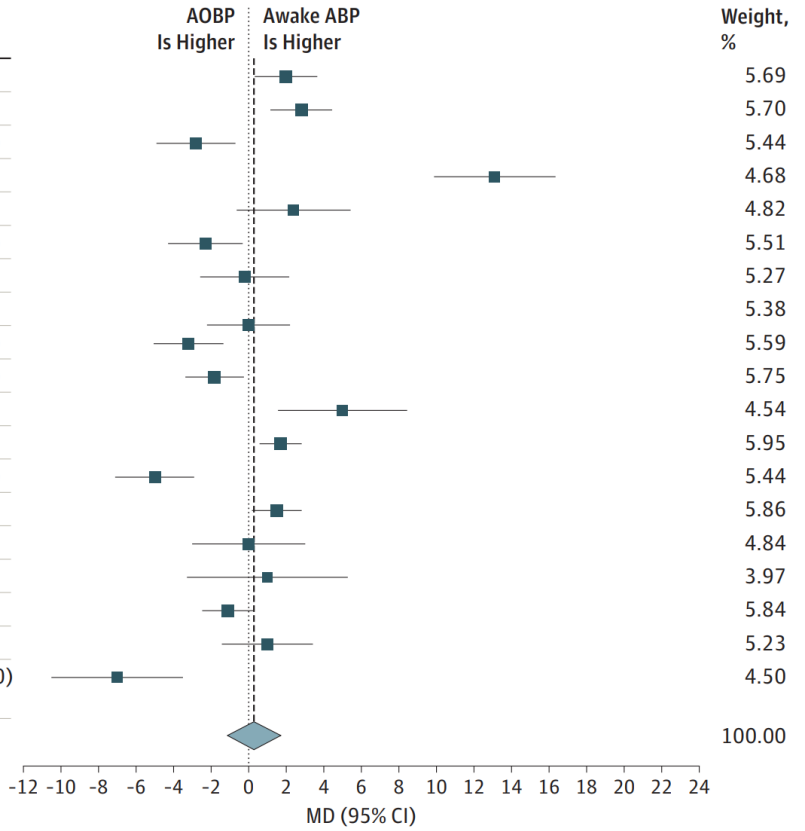
- Limitations
  - Cost
  - Require validation
    - Only 2 validated monitors currently available
  - Require adjustment in workflow
  - Does not overcome poor patient positioning

Cohen JB and Cohen D. *Curr Cardiol Rep* 2016; 18

Automated office blood pressure

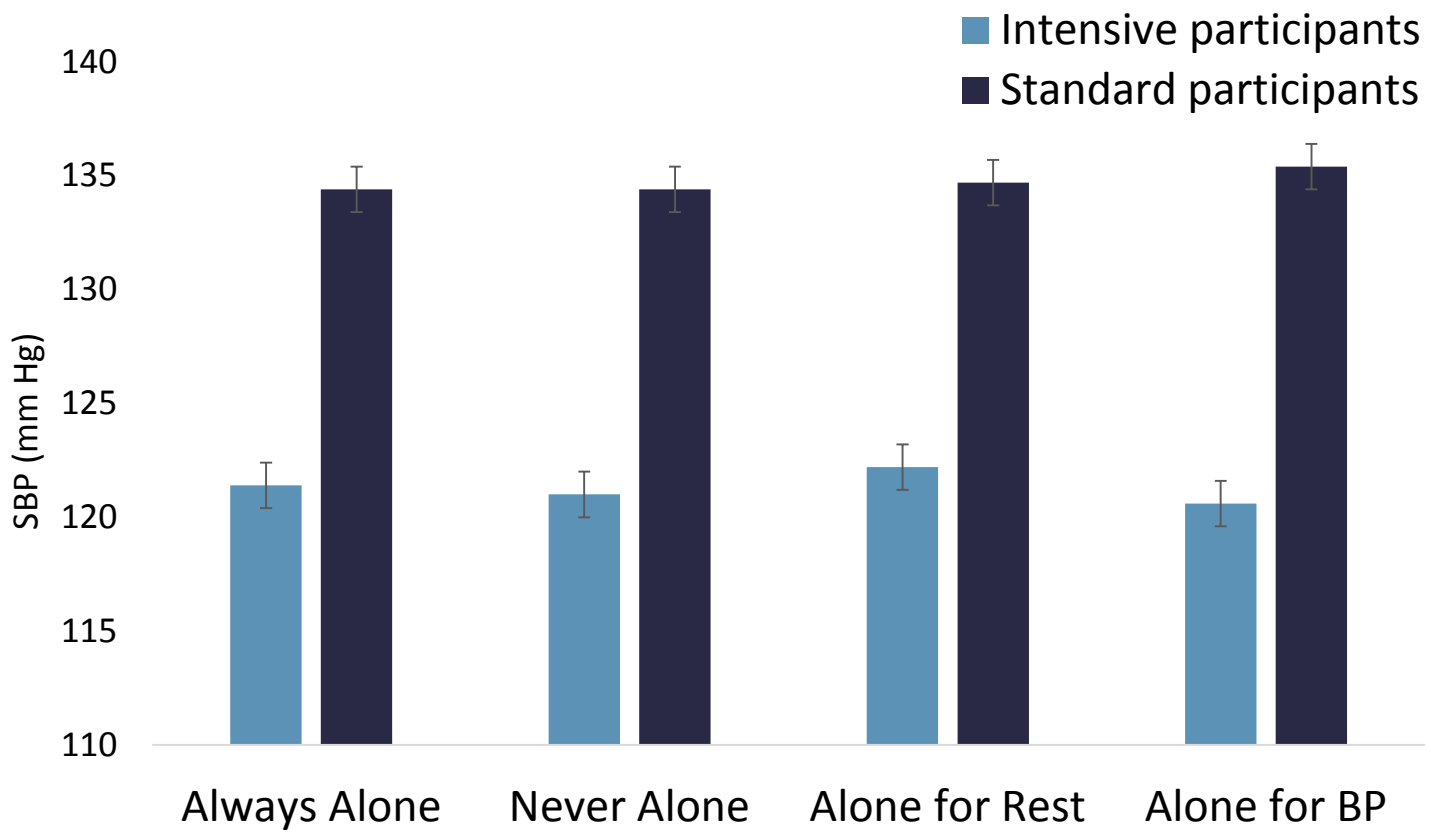
Figure 1. Mean Difference (MD) in Systolic Blood Pressure Between Automated Office Blood Pressure (AOBP) (Reference) and Awake Ambulatory Blood Pressure (ABP) Measurement in Samples With Systolic AOBP of 130 mm Hg or Higher

Source	AOBP, mm Hg	No. of Patients	MD (95% CI)	Weight, %
Myers et al,[33] 2009	132.0	309	2.00 (0.33 to 3.67)	5.69
Myers,[34] 2010	132.6	254	2.80 (1.15 to 4.45)	5.70
Myers et al,[39] 2012	133.1	252	-2.80 (-4.90 to -0.70)	5.44
Ringrose et al,[41] 2018	133.3	76	13.10 (9.86 to 16.34)	4.68
Ishikawa et al,[18] 2012	134.7	87	2.40 (-0.63 to 5.43)	4.82
Myers et al,[38] 2011	135.6	299	-2.30 (-4.29 to -0.31)	5.51
Padwal et al,[16] 2015	135.7	100	-0.20 (-2.57 to 2.17)	5.27
Moore et al,[14] 2018	136.0	189	0.00 (-2.21 to 2.21)	5.38
Edwards et al,[15] 2013	136.3	329	-3.20 (-5.06 to -1.34)	5.59
Myers et al,[40] 2012	138.6	100	-1.80 (-3.36 to -0.24)	5.75
Myers et al,[30] 2008 (1 min)	139.0	104	5.00 (1.56 to 8.44)	4.54
Godwin et al,[36] 2011	139.2	654	1.70 (0.57 to 2.83)	5.95
Andreadis et al,[47] 2012	139.9	139	-5.00 (-7.11 to -2.89)	5.44
Beckett et al,[27] 2005	140.0	481	1.50 (0.17 to 2.83)	5.86
Myers et al,[30] 2008 (2 min)	140.0	100	0.00 (-3.01 to 3.01)	4.84
Myers et al,[32] 2009	140.0	62	1.00 (-3.27 to 5.27)	3.97
Armstrong et al,[10] 2015	140.5	422	-1.10 (-2.47 to 0.27)	5.84
Myers et al,[35] 2010	141.0	139	1.00 (-1.43 to 3.43)	5.23
García-Donaire et al,[51] 2012 (TRUE-HTA)	144.4	101	-7.00 (-10.50 to -3.50)	4.50
Overall effect: $I^2 = 89.5\%$; $P < .001$			0.29 (-1.13 to 1.71)	100.00



Roerecke M et al. *JAMA Intern Med* 2019; 179(3):351-62

Automated office blood pressure: observed vs. unobserved measurements in SPRINT



Johnson KC et al. *Hypertension* 2018; 71(5)

ACC/AHA 2017 Guideline for the Prevention, Detection, Evaluation of High Blood Pressure in Adults

COR	LOE	Recommendation for Out-of-Office and Self-Monitoring of BP
I	A^{SR}	**Out-of-office BP measurements are recommended** to confirm the diagnosis of hypertension and for titration of BP-lowering medication, in conjunction with telehealth counseling or clinical interventions.

Whelton PK et al. *J Am Coll Cardiol* 2018; 71(19)

Many of the limitations of in-office BP are mitigated by out-of-office BP measurement

Registry-based, multicenter, national cohort of 63,910 patients

To assess the associations of BP measured in the clinic (clinic blood pressure) and 24-hour ambulatory bp with all-cause and cardiovascular mortality

MASKED HTN
(→ clinic SBP, ↑ 24 h SBP)
Mortality:
HR 2.83 (2.12-3.79)

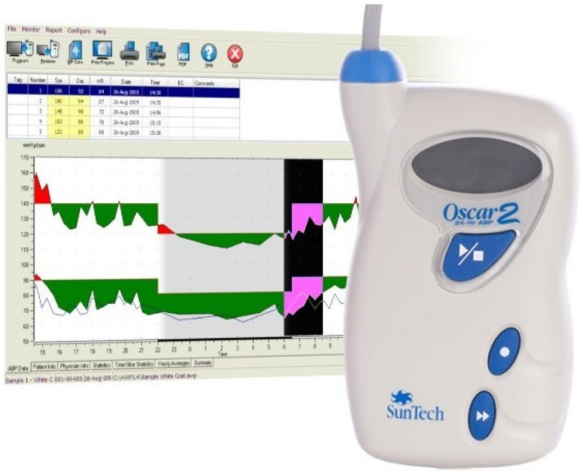
ELEVATED CLINIC SBP
Mortality:
HR 1.02 (1.00-1.04)

SUSTAINED HTN
(↑ clinic SBP, ↑ 24 h SBP)
Mortality:
HR 1.80 (1.41 to 2.31)

Banegas JR et al. *N Engl J Med*. 2018;378(16)

Out-of-office BP measurement is prognostically superior to in-office BP measurement

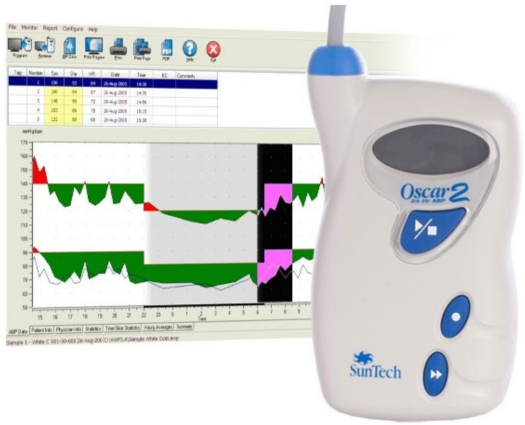
- More strongly associated with progression of CKD, cardiovascular disease (CVD), and mortality in the general population
  - 24-hour ambulatory BP monitoring (ABPM)
  - Home BP monitoring (HBPM)



Banegas JR et al. *N Engl J Med*. 2018;378(16)
Cohen JB and Cohen DL. *Curr Cardiol Rep*. 2016;18(11)

Distinctions between 24-hour ABPM and HBPM

- 24-hour ABPM
  - Worn for 24-hours, measurements every 20-30 minutes during the day, every 60 minutes at night
  - “Gold standard” of out-of-office BP measurement due to its ability to detect white coat effect, masked hypertension, and nocturnal non-dipping



millionhearts.hhs.gov

Cohen JB et al. *Hypertension* 2019; 73:258-264

Distinctions between 24-hour ABPM and HBPM

- Home BP monitoring (HBPM)
  - Ideally, two measurements in the morning (between 7-10am), two measurements in the evening (between 7-10pm) for 5-7 consecutive days, once a month
  - Improves upon in-office BP measurement by eliminating white coat effect and identifying some masked hypertension
  - Ideal for longitudinal out-of-office BP monitoring due to easy access to monitors and simplicity of interpretation

Cohen JB et al. *Hypertension* 2019; 73:258-264

Implementing home blood pressure monitoring in practice

Table 5. Preferred Characteristics of a Home Blood Pressure Monitor[3]	
Preferred	**Not Preferred**
Automated	Manual
Upper arm cuff	Wrist cuff*
Properly sized cuff	Too-large or too-small cuff
Memory storage capacity	No memory storage
Printing capacity	No printer
Ability to upload BP readings to computer or other electronic device	No ability to upload
Accuracy checked by clinician after purchase	Patient uses monitor without consulting clinician

Benefits of out-of-office blood pressure

- Multiple readings
- Strongest prognostic association with cardiovascular outcomes
- Reduce human error
- Identify white coat hypertension/effect and masked hypertension

Cohen JB and Cohen D. *Curr Cardiol Rep* 2016; 18

Physician-level barriers to out-of-office blood pressure monitoring

Ambulatory Blood Pressure Monitoring	Home Blood Pressure Monitoring
Limited reimbursement	No Reimbursement
Time-consuming interpretation of results	Time-consuming patient education
Device cost	
Device validation	
No standard for assessing quality of measurements	

Cohen JB and Cohen D. *Curr Cardiol Rep* 2016; 18

Patient-level barriers to out-of-office blood pressure monitoring

Ambulatory Blood Pressure Monitoring	Home Blood Pressure Monitoring
Limited access	Longitudinally time-consuming
Often only available in hypertension clinics	Device cost
Temporary intrusion into day-to-day activities	Device validation
Sleep disturbance	Requires literacy

Cohen JB and Cohen D. *Curr Cardiol Rep* 2016; 18

2017 ACC/AHA Guideline for the Prevention, Detection, Evaluation of High Blood Pressure in Adults

Clinic BP level	To screen for:
SBP 120-129 mm Hg and DBP 75-79 mm Hg	Masked [uncontrolled] hypertension
SBP ≥ 130 mmHg or DBP ≥ 80 mm Hg	White coat hypertension [effect]

Whelton PK et al. *J Am Coll Cardiol* 2018; 71(19)

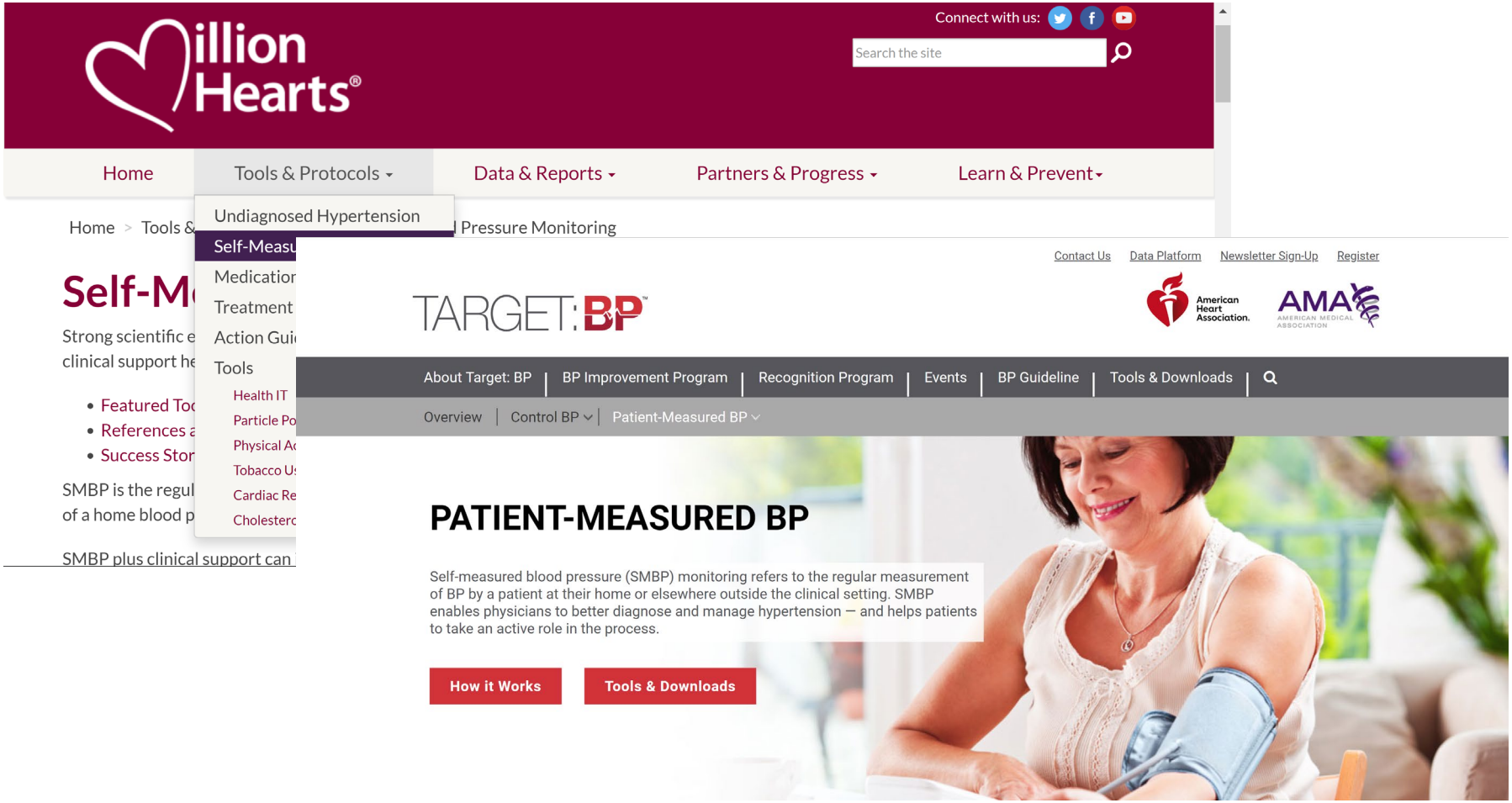
Corresponding values for in- vs. out-of-office measurements

Clinic	HBPM	Daytime ABPM	Nighttime ABPM	24-Hour ABPM
120/80	120/80	120/80	100/65	115/75
130/80	130/80	130/80	110/65	125/75
140/90	**135/85**	**135/85**	120/70	130/80
160/100	145/90	145/90	140/85	145/90

Whelton PK et al. *J Am Coll Cardiol* 2018; 71(19)

Table 7. Current Insurance Coverage/Reimbursement of Home Blood Pressure Monitors and Additional Support	
Coverage Type	**Benefits**
Medicare Part B (Traditional fee-for-service Medicare)	• Covers ambulatory blood pressure monitoring.[3] • Covers physician interpretation of results for the diagnosis of white coat hypertension.[3] • Does not cover home blood pressure monitors used for SMBP. • Does not cover clinician interpretation of readings for treatment of hypertension.
Medicare Part C (Medicare Advantage Plans)	• Not mandated, but may cover supplemental coverage of home blood pressure monitors or additional support programs for enrollees.[45]
Medicaid	• Coverage for home blood pressure monitors and additional support varies by state.
Private insurance carriers and self-insured employers	• Decision to cover home blood pressure monitors and additional support is made by each individual plan • Some private insurance plans provide these types of benefits only for beneficiaries who are enrolled in disease-management programs for hypertension or other medical conditions that increase the risk of heart disease and stroke.[46] • HCPCS code S9110 can be used by private insurers, but not CMS, for home telehealth reimbursement.

How to get patients engaged



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targetbp.org

How to measure your blood pressure at home

Follow these steps for an accurate blood pressure reading

1 PREPARE

Avoid caffeine, cigarettes and other stimulants 30 minutes before you measure your blood pressure.

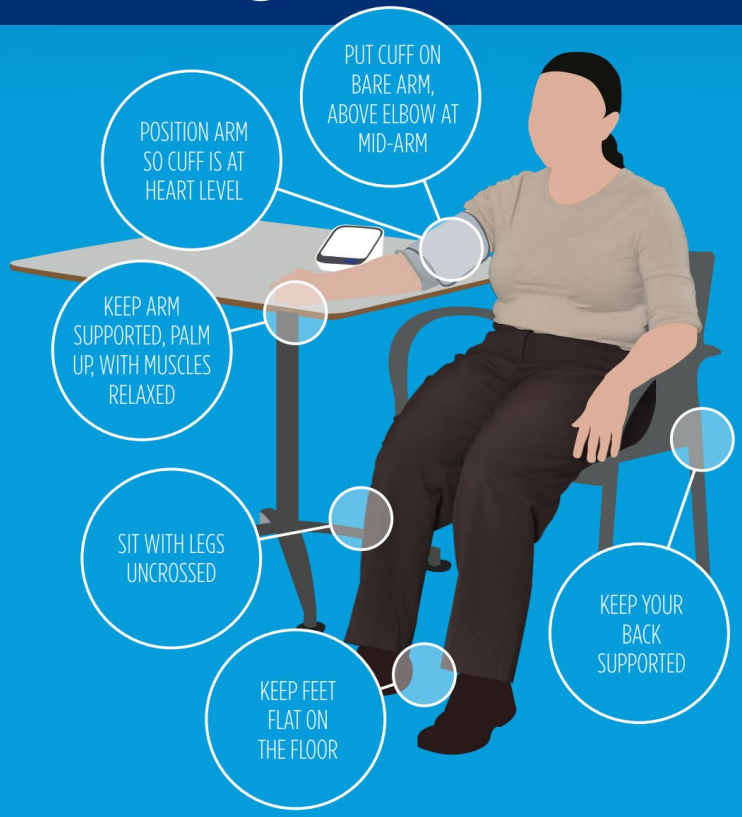
Wait at least 30 minutes after a meal.

If you're on blood pressure medication, measure your BP **before** you take your medication.

Empty your bladder beforehand.

Find a quiet space where you can sit comfortably without distraction.

2 POSITION



3 MEASURE

Rest for five minutes while in position before starting.

Take two or three measurements, one minute apart.

Keep your body relaxed and in position during measurements.

Sit quietly with no distractions during measurements—avoid conversations, TV, phones and other devices.

Record your measurements when finished.

Self-measured blood pressure

Using a wrist cuff* to measure blood pressure

* When an upper arm cuff cannot be used, validated wrist devices can be used for blood pressure estimation.[1]

Correct forearm position
for wrist blood pressure measurement

1. **Apply the wrist device**
2. **Keep elbow on table or desk with forearm bent**
3. **Place the wrist at heart level**
4. **Keep arm relaxed and hand resting against your body**
5. **Measure wrist blood pressure without moving arm from seated position**

Incorrect forearm position[2]

Wrist higher than heart level

Forearm in horizontal position

Forearm vertical and close to the body

Additional tools for optimizing measurement quality

Evaluating blood pressure device validation

- Most clinicians:
  - Rely on the lay news for information regarding concerns about devices

Smartphone app misreads hypertension range

Lisa Rapaport

Published 6:06 PM ET Wed, 2 March 2016

REUTERS

Evaluating blood pressure device validation

- Validated device listings

VDL Criteria	American Medical Association	Hypertension Canada	British and Irish Hypertension Society
Accepted methods for summarizing validation data	Peer-reviewed publication	Peer-reviewed publication	Peer-reviewed publication
	Unpublished independent third-party validation study		Society-performed validation study
Listed devices	Only recommended devices	Only recommended devices	Recommended and nonrecommended devices

Cohen JB et al. *Hypertension* 2019; 73:258-264

Evaluating blood pressure device validation

	Device	Validation protocol	Upper arm cuff sizes	Features	Software and technological features	Device cost
ABPM upper arm devices for clinical use	SpaceLabs Healthcare[a] 90227 OnTrak	BHS: A/A ESH: Pass (2010)	Child, 12-20 cm Adult (small), 17-26 cm Adult (standard), 24-32 cm Adult (large), 32-42 cm Adult (extra-large), 38-50 cm, includes cuff support harness	300 readings; 2 AA batteries; developed for use in pediatric patients aged 3-12 y; inflation pressure can be set to 110, 130, 150, or 170 mm Hg	$850, single computer license $3500-$4000, 2 network licenses and training	$2400
	SpaceLabs Healthcare[a] 90217A Ultralite	AAMI: Pass BHS: A/A		270 readings; 3 AA batteries; developed for use in pediatric patients aged ≥6 y	$850, single computer license $3500-$4000, 2 network licenses and training	$2400 + $117 for cable
	Microlife WatchBP O3	ESH: Pass (2002)	Medium, 22-32 cm Large, 32-42 cm	Programmable measurement modes for ambulatory, home, and clinic; programmable time intervals of 15, 20, 30, and 60 min for ambulatory monitoring; automatic recording button for time medication is taken	Free software download from company website	$1995
HBPM upper arm devices	Omron Healthcare Evolv BP7000	ESH: Pass (2010)	Adjustable, 22.9-43.2 cm	No averaging of BP measurements; no internal device memory for BP measurements	Wireless monitor attached to cuff; Bluetooth connection to free mobile app via smartphone or tablet; spreadsheet feature to email BP measurements to user or physician	$99.99
	Omron Healthcare BP786N	ESH: Pass (2010)	Adjustable, 22.9-43.2 cm	Feature for averaging 3 readings with set rest time between readings; internal device memory saves 200 readings	Wireless with device monitor and cuff separated by air tube; Bluetooth connection to free mobile app via smartphone or tablet	$64.99 to $69.99
	A&D Medical UA-651BLE	ESH: Pass (2010)	Standard, 22.9-37.1 cm Large, 31.0-45.0 cm	No averaging of BP measurements; no automatic series of measurements; internal device memory saves 30 readings with date and time stamps	Free download of A&D Connect mobile app software; wireless device to send and store unlimited measurements on Bluetooth-enabled phone or tablet	$49.99
	Panasonic Ew3109	ESH: Pass (2002)	Standard, 19.7-40.0 cm Large, 34.9-43.8 cm	Single measurements only	Automatic memory of 90 readings	$49.76 to $52.00

Melville S and Byrd JB. *JAMA* 2018; 320(17):1805-6

Individual device validation

Cohen JB et al. *Hypertension* 2019; 73:258-264

Individual device validation

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

Future directions

FDA cleared, awaiting external validation

Cuffless Technology

- **Caution**: not FDA cleared, not recommended for clinical use

ThinkBand™ Blood Pressure Smart Watch And Heart Rate Monitor

★★★★★ (31)

$34.95 ~~$109.95~~ SAVE 68%

Color: Gold

Quantity: − 1 +

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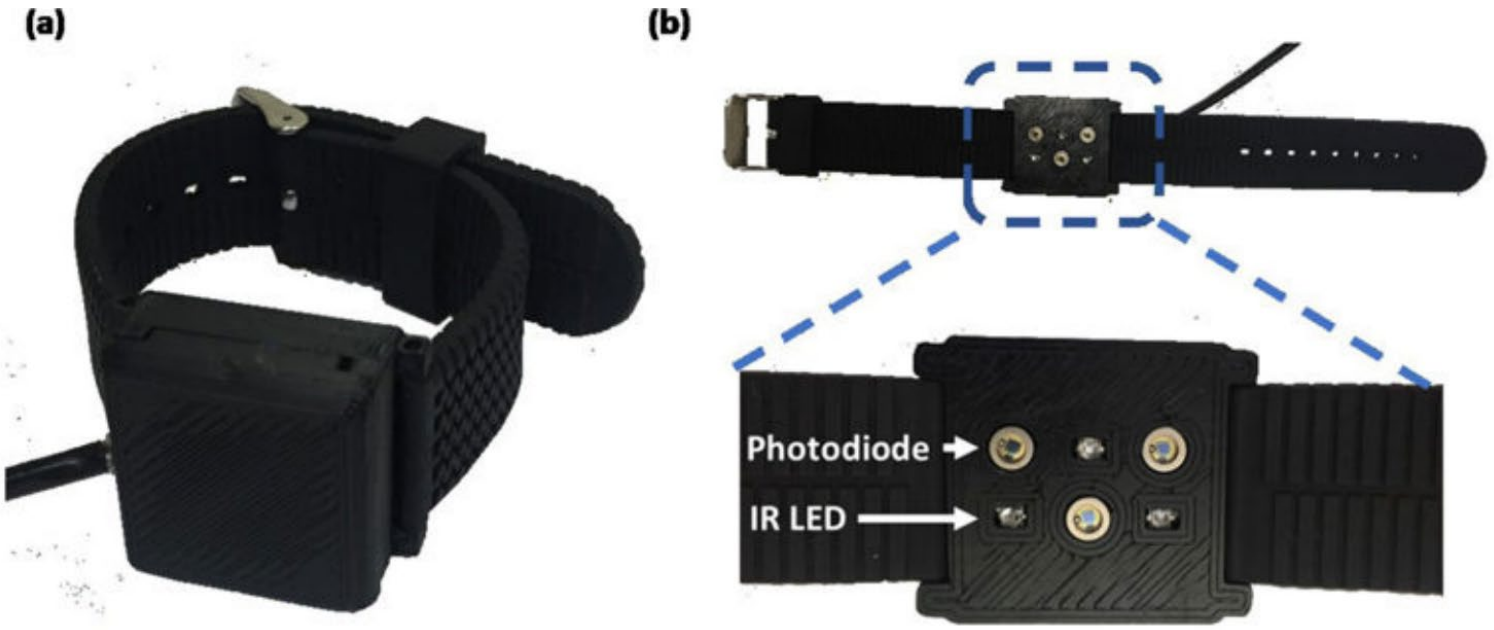
Cuffless Technology: tonometry (pulse transit time)

- **Caution**: not FDA cleared, not recommended for clinical use



Carek AM et al. Proc ACM Interact Mob Wearable Ubiquitous Technol. 2017; 1(3): 40

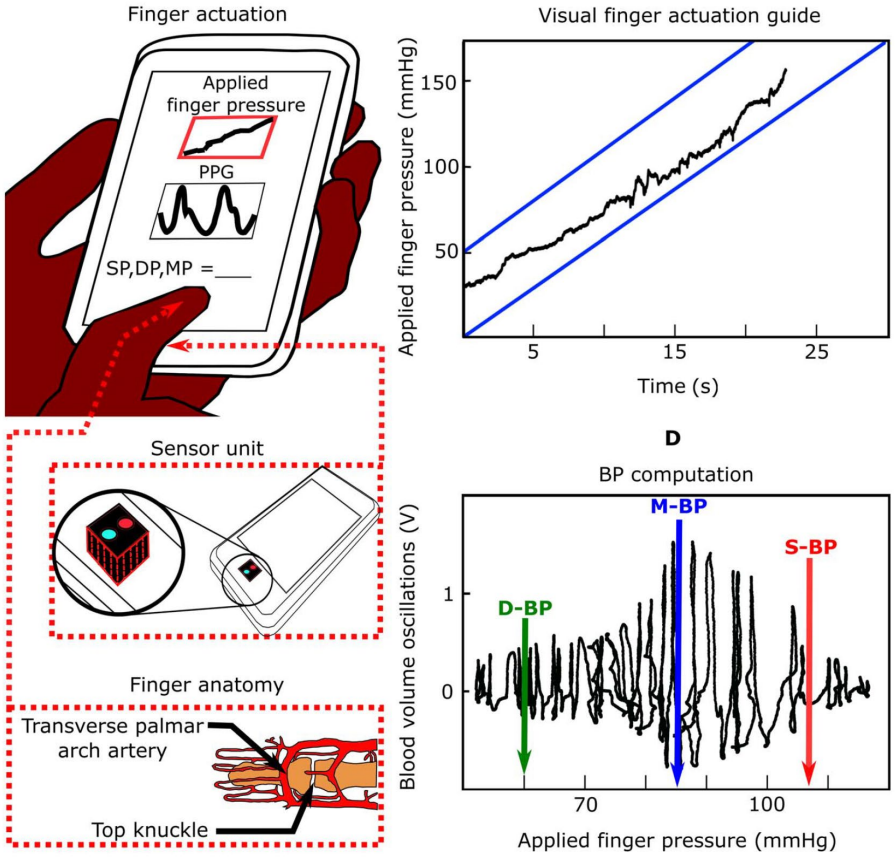
Cuffless Technology: Magnetoplethysmography

- **Caution**: not FDA cleared, not recommended for clinical use

Kim S et al. *Pulse.* 2018;6:9-18

Cuffless Technology: finger plethysmography

- **Caution**: not FDA cleared, not recommended for clinical use



Chandrasekhar A et al. *Sci Transl Med.* 2018 Mar 7;10(431)

Finger blood pressure cuffs

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Summary of the current landscape

- There are several important shortcomings in typical clinic BP measurement
- With the recent hypertension guideline and metric-based reimbursement, it is important to improve upon current methods to measure BP
- Automated office blood pressure (AOBP) has the potential to overcome several deficiencies in the diagnosis and management of hypertension
  - However, device validation is critical to ensuring accurate BP assessment
  - Cannot adequately assess for high risk abnormalities, such as masked hypertension and non-dipping
- Out-of-office blood pressure measurement is critical to the measurement and management of hypertension
- Practice caution with regard to the validity of available devices on the market; valid finger and cuffless devices are not yet available

Questions?