IEEE 1708 Cuffless Blood Pressure Standard

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Outline

- Introduction
- Review on current standards
- Error distribution model
- Data analysis
- Validation protocol design
- summary

AHA/ASH/PCNA Scientific Statement

Call to Action on Use and Reimbursement for Home Blood Pressure Monitoring: Executive Summary [1]

In 2008, the American Heart Association (AHA), American Society of Hypertension (ASH), and Preventive Cardiovascular Nurses Association (PCNA) published a joint scientific statement that recommended :

Home Blood Pressure Measurement (HBPM) should become a routine component of BP measurement in the majority of patients with known or suspected hypertension.

[1]T. G. Pickering, *et al. Hypertension*, 2008.

Cuffless Blood Pressure Measurements

Advantages

- **Real-time**
- **Continuous**
- **Non-invasive BP**
- **Miniature in size**
- **Low power consumption**

Problem: Are they accurate?

Needs for A New Standard

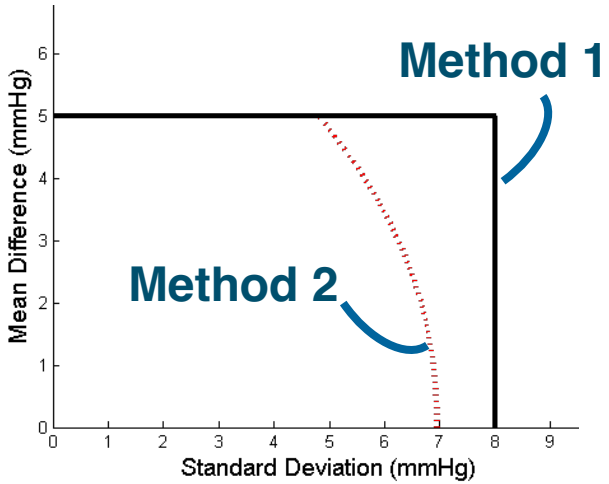
- **A standard on evaluation of cuff-less devices is needed,**
  - **For device developers to qualify and validate their products;**
  - **For potential purchasers to select prospective products;**
  - **For health care professionals to understand the manufacturing practices on wearable cuff-less BP devices.**
- In 2014, "**IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices**" (IEEE 1708) has been published.
  - **Validation protocol**
  - **Statistical analysis**
  - **Wearable sensors/communications**

Objectives

- In this session, we will focus on the following aspects:
  - **Error distribution model** of various BP measuring devices;
  - **Evaluation parameters** for assessing the accuracy of cuff-less devices; and
  - **Validation protocol design** that meets the special features of cuff-less devices.

Standard by American Association for the Advancement of Medical Instrumentation

- **Publication Time:** first published in 1986, revised twice in 1993, 2003.
- **Subject:** at least **85**, each of them contributes **3** measurements
- **Data Analysis:**
  - **Accuracy Measurement:** Statistical **mean difference** (**MD**) and **standard deviation of differences** (**SD**) between the measurements obtained by a test device and the reference
  - **Accuracy Criteria:**
    - **Method 1:** MD and SD of all measurement differences (N = 255) be within ± 5 mmHg and 8 mmHg respectively.
    - **Method 2:** averages the 3 readings of each subject and reduces the allowable value of the SD as the MD increased.



Protocol by British Hypertension Society

- **Publication Time:** first established in 1990, revised in 1993
- **Subject:** at least **85**, each of them contributes **3** measurements
- **Data Analysis:**
  - **Accuracy Measurement:** percentages of measurement difference lying within 5, 10 and 15mmHg (**$CP_{5,10,15}$**).
  - **Accuracy Criteria:** device is **graded into A, B, C or D** if it meets all the requirements on the $CP_{5,10,15}$.

British Hypertension Society Grading Criteria (2002)			
Grade	Absolute difference between standard and test device (mmHg)		
	≤5	≤10	≤15
Cumulative percentage of readings (%)			
A	60	85	95
B	50	75	90
C	40	65	85
D	Worse than C		

Problem Description

Accuracy Discrepency under Normal Distribution

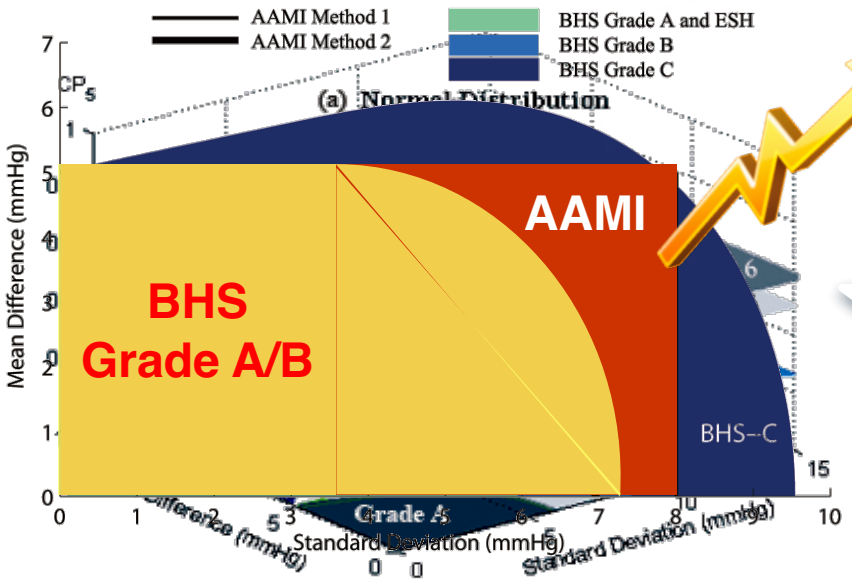
PDF for normal distribution

$$p(x \mid u,d)dx = \frac{1}{d\sqrt{2\pi}} e^{\frac{-(x-u)^2}{2d^2}}$$

Relationship between MD, SD and CP

$$\mathrm{CP}_L{}^g(u,d,L) = \frac{1}{d\sqrt{2\pi}} \int_{-L}^{L} e^{\frac{-(x-u)^2}{2d^2}} dx$$

Relationship of BHS and AAMI criteria under normal distribution[1]



BHS grading higher than B ensures passing of AAMI

However, there actually were devices that passed BHS but failed AAMI [2]

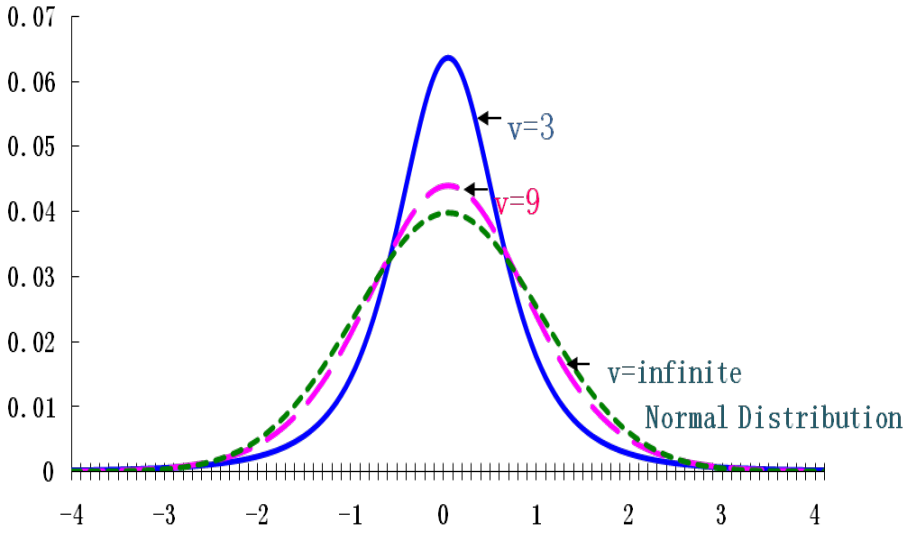
Normal model may not be a good approximation.

[1] M. Sun and R. Jones, *Biomed Instrum Technol*, 1999. [2] X.Y. Xiang *et al. 3rd IEEE-EMBS*, 2006

Generalized t Distribution

- **Comparing to normal distribution**
  - **degree of freedom (*v*) controls the shape of the PDF in terms of the height of peak and the thickness of tail.**

t distribution with different value of v



PDF for generalized t distribution

$$p(t\,|\,u,s,v)=\frac{s^{-1}\Gamma(\frac{v+1}{2})}{\Gamma(\frac{v}{2})\sqrt{v\pi}}\times\left(1+\frac{(t-u)^2}{s^2 v}\right)^{-\frac{v+1}{2}}$$

Relationship between MD, SD and CP

$$\mathrm{CP}_L^{\,t}(u,d,v,L)=\int_{-L}^{L}p(t\,|\,u,d,v)dt=\frac{d^{-1}\Gamma(\frac{v+1}{2})}{\Gamma(\frac{v}{2})\sqrt{(v-2)\pi}}\int_{-L}^{L}\left(1+\frac{(t-u)^2}{d^2(v-2)}\right)^{-\frac{v+1}{2}}dt$$

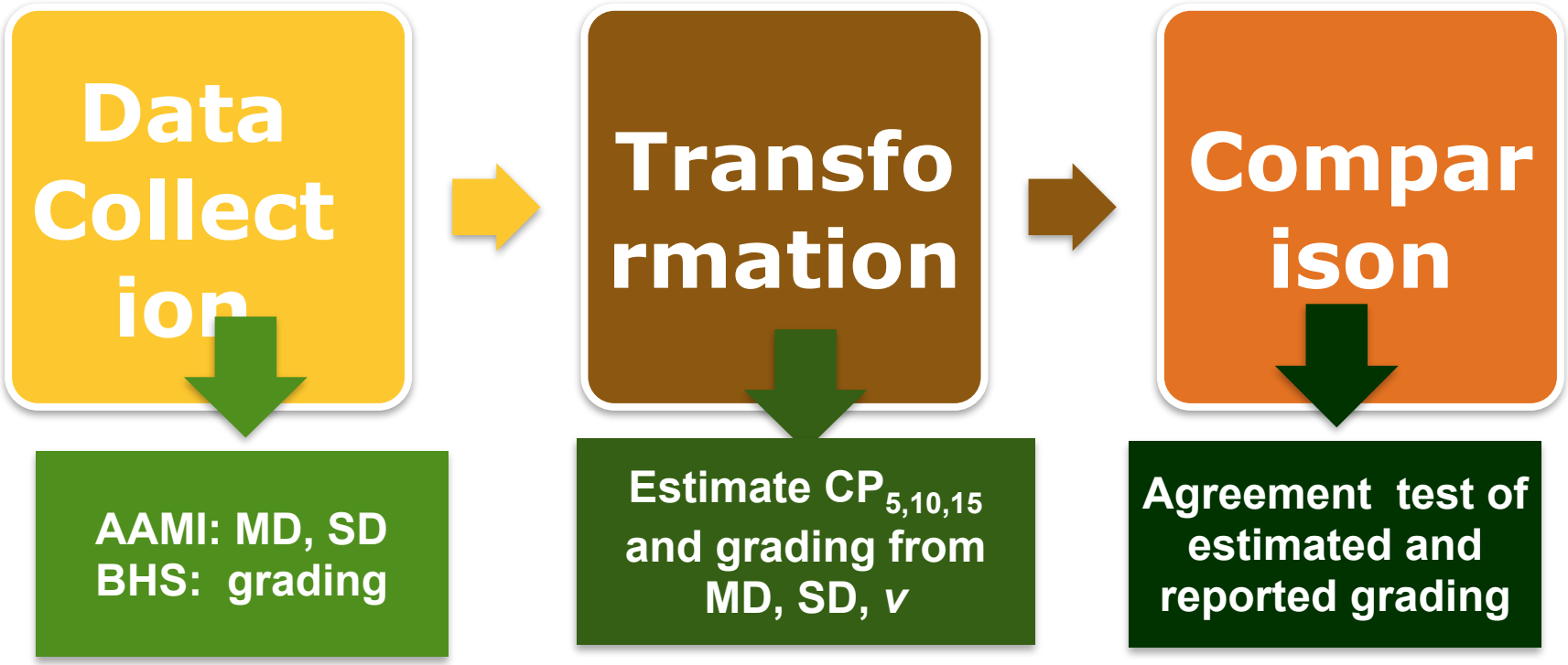
u: MD, *s:*scalar parameter and equals to $\mathrm{SD}\cdot\sqrt{(v-2)/\pi}$ (v>2), *v:* degrees of freedom

As the value of *v* grows, the generalized t distribution approaches the normal distribution.

Analysis on Cuff-based Devices

Methodology

- **Comprehensive search in the Medline database for literatures published during 1991 to 2008 on the evaluation of BP devices by the BHS protocol and the AAMI standard.[1]**



[1] R.F. Yan *et al. Blood Press Monit*, 2009

Analysis on Cuff-based Devices

Estimation Results under Normal and t4 Distribution

(a) Normal Distribution

SBP

Reported BHS Grading	Estimated BHS Grading A	B	C	D
A	**18**	13	2	0
B	0	**1**	2	2
C	0	0	**0**	1
D	0	0	0	**1**

chi-square=18.9 (p=0.0003),
Matches%=**50%**

DBP

Reported BHS Grading	Estimated BHS Grading A	B	C	D
A	**17**	12	3	0
B	1	**0**	3	0
C	0	0	**0**	3
D	0	0	0	**1**

chi-square=17.3 (p=0.0006),
Matches%=**45%**

(b) t4 Distribution

SBP

Reported BHS Grading	Estimated BHS Grading A	B	C	D
A	**29**	4	0	0
B	0	**3**	2	0
C	0	0	**0**	1
D	0	0	0	**1**

chi-square=7.0 (p=0.07),
Matches%=**83%**

DBP

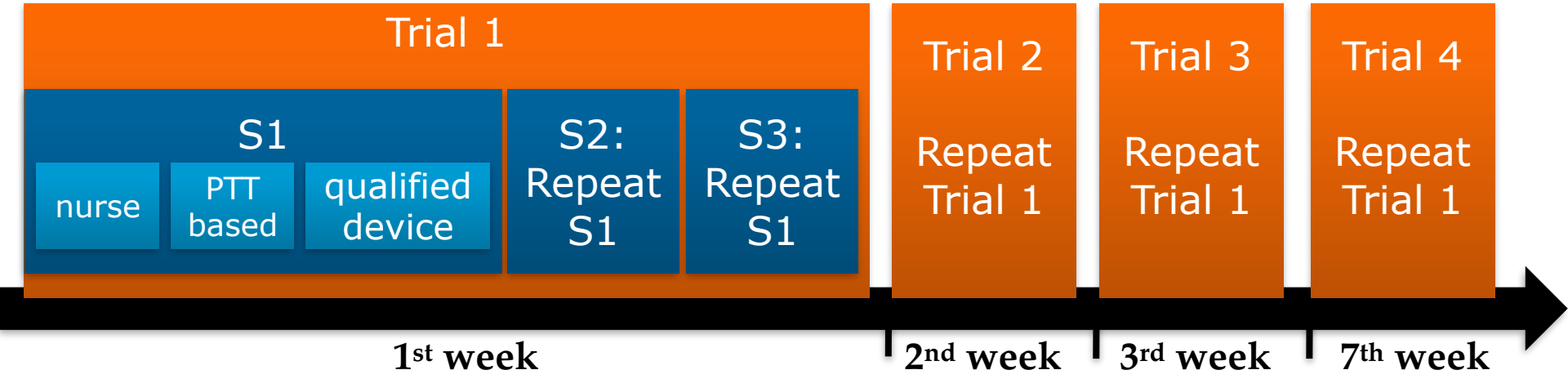
Reported BHS Grading	Estimated BHS Grading A	B	C	D
A	**27**	5	0	0
B	1	**2**	1	0
C	0	0	**2**	1
D	0	0	0	**1**

chi-square=4.7 (p=0.2), Matches%=**80%**

Analysis on Wearable Cuff-less Device

Methodology

85 subjects, aged 57±29yrs, 36 males, 39 with hypertension, **999** pairs of readings. [1]



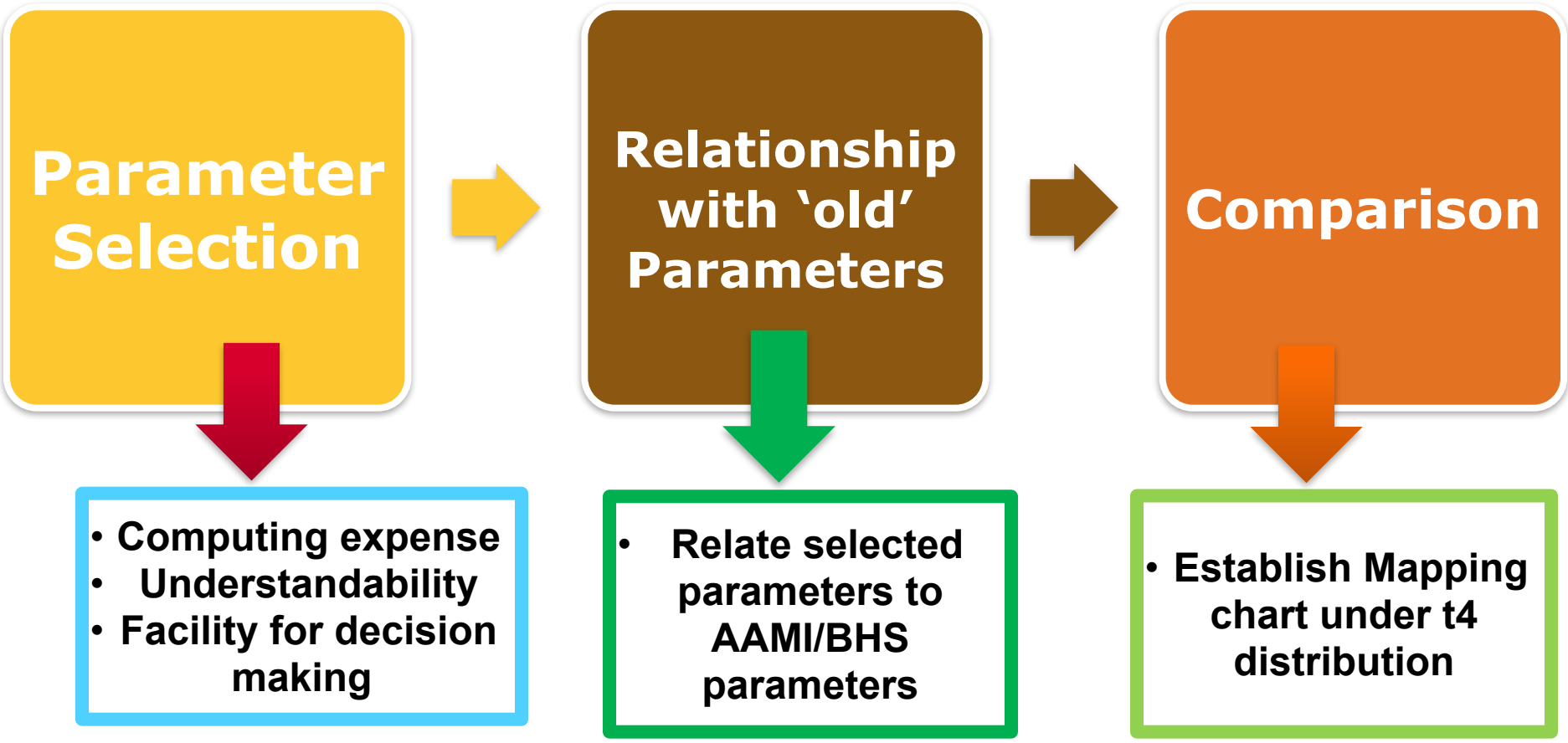
Data Analysis:

- Estimate BHS grading from MD and SD under normal or t4 distribution, and test the accordance with the reported grading.
- Fitting the distribution of measuring differences to normal and t4 distribution.
- Assess the goodness-of-fit to by Kolmogorov-Smirnov (KS) test.

[1] C. C. Poon *et al. 27th EMBS,* 2005.

Parameter Selection

Methodology



[1] R.F. Yan *et al. Blood Press Monit*, 2009

Selected Parameters

Definition & Relationship under t4 Distribution

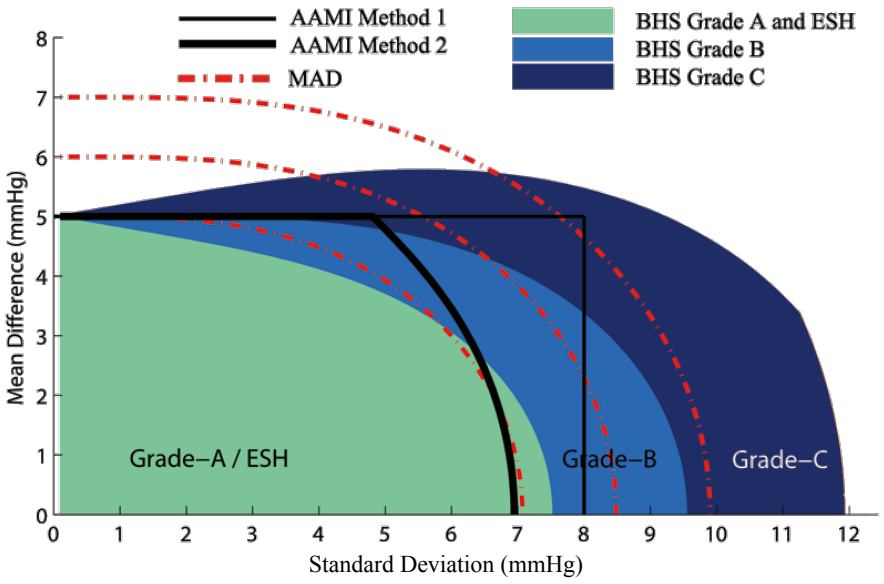
Parameter Definition	Relationship with MD & SD
Mean Absolute Difference (MAD)	
$$MAD = \left(\sum_{i=1}^{n} \lvert p_i - y_i \rvert\right) / n$$	$$MAD = 2s\sqrt{\frac{v}{\pi}}\frac{\Gamma(\frac{v+1}{2})}{\Gamma(\frac{v}{2})(v-1)}(1+\frac{u^2}{s^2 v})^{-\frac{v-1}{2}} + \lvert u \rvert \cdot (1 - I(\frac{v}{v+(\frac{u}{s})^2}; \frac{v}{2}, \frac{1}{2})$$
Root Mean Square Difference (RMSD)	
$$RMSD = \sqrt{\left(\sum_{i=1}^{n} (p_i - y_i)^2\right) n}$$	$$RMSD = u^2 + d^2$$
Mean Absolute Percentage Difference (MAPD)	
$$MAPD = \left(\sum_{i=1}^{n} \lvert 100(p_i - y_i)/y_i \rvert\right) / n$$	NA

* p_i is the measured value, y_i is the reference value and n is the data size, u is MD, d is SD, v is degree of freedom of t distribution

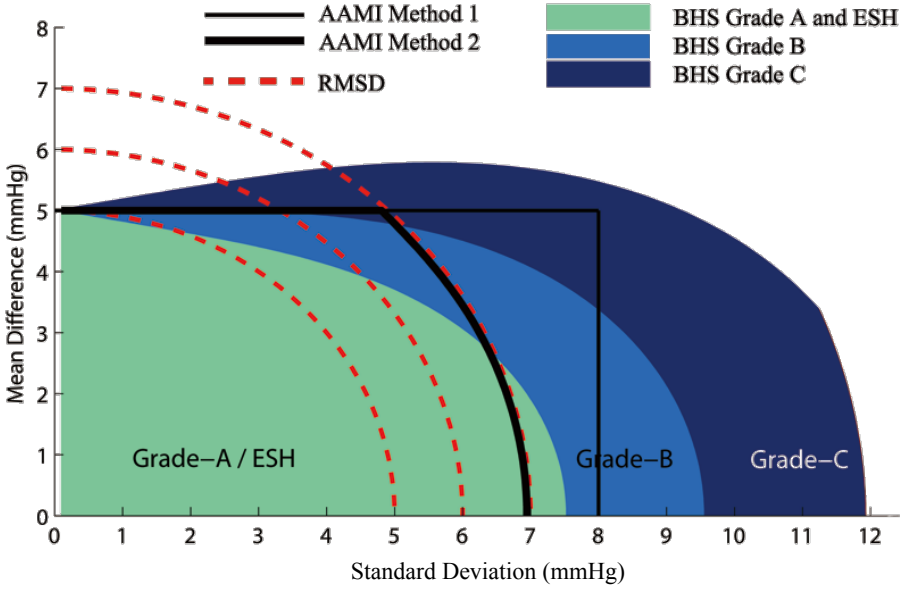
Parameters Selection

Relationship between 'New' and 'Old' Parameters

(a) MAD



(b) RMSD



(a) MAD and (b) RMSD as a function of MD and SD under t4 distribution. The red lines are MAD or RMSD with values equal to 5, 6 and 7 mmHg from inter to outer.

[1] R.F. Yan *et al. Blood Press Monit*, 2009

Discussion

Accuracy Criteria

MAD accuracy level with comparison to the AAMI and BHS evaluation systems.		
MAD (mmHg)	**Method 1 of AAMI**	**BHS**
≤4	pass	Grade A
4-5	pass	mostly Grade A, few Grade B
5-6	pass or fail	mostly Grade B, few Grade A, extremely few Grade C/D
6-7	mostly fail, less pass	mostly Grade C, few Grade B/D
≥7	fail	worse than Grade C

Cuffless BP device

Subject Dependent Calibration

- **Cuff-less devices should be calibrated individually.**
- **Cuff-less devices should be calibrated frequently.**
- **Effective calibration should be done before and after a period time of use, with wide enough range of BP change.**
- **When devices claim to provide continuous measurement in the daily life, 24-h device assessment is necessary.**

Accuracy after a certain period of time

Cuff-based Device, Study 1

Device accuracy report for systolic blood pressure measurement (Study 1, N=999, Cuff-based Device)								
BP Change (mmHg)	**MAD (mmHg)**	**MAPD (%)**	**MD (mmHg)**	**SD (mmHg)**	**CP_5 (%)**	**CP_{10} (%)**	**CP_{15} (%)**	**Grading**
Overall (N=999)								
7.7	5.8	4.7	-2.8	7.2	56.7	86.1	95.6	B
Accuracy for different trials								
Trial 1 (N=255)								
3.9	5.6	4.5	-2.6	6.7	58.8	87.1	95.3	B
Trial 2 (N=255)								
9.3	5.8	4.6	-2.9	6.6	54.1	86.3	95.3	B
Trial 3 (N=255)								
8.4	5.8	4.8	-3.2	6.8	58.8	84.7	95.7	B
Trial 4 (N=234)								
9.3	5.9	4.8	-2.5	7.0	55.1	86.8	96.6	B

Accuracy after a certain period of time

Cuff-based Device, Study2

Device accuracy report for systolic blood pressure measurement (Study 2, N=139, Cuff-less Device)							
BP Changes (mmHg)	**MAD (mmHg)**	**MAPD (%)**	**MD (mmHg)**	**SD (mmHg)**	**CP_5 (%)**	**CP_{10} (%)**	**CP_{15} (%)**
Overall (N=139)							
12.6	6.8	5.7	-2.3	9.0	49.6	74.8	88.5
Before or after exercise							
Before Exercise (N=56)							
2.1	2.9	2.8	0.5	3.9	82.1	98.2	100.0
After Exercise (N=83)							
19.7	9.4	7.6	-4.2	10.8	27.7	59.0	80.7

Discussion

- Since the cuff-less devices require a calibration procedure, evaluation shall be with a wide range of BP change from the calibration point.
- Evaluating the performance of cuff-less devices concerning the change of BP from calibration point is crucial for interpreting the overall accuracy .
- The protocol may also need to cover a wide enough range of time, in order to assess whether the calibration of the device ages as well as it has claimed.

Accuracy Assessment with BP Change

Inducement of Blood Pressure Change

- Assuming that 45 subjects are recruited to contribute a total of 135 datasets, the number of datasets that is required for each range is also included in the table.

Inducement of blood pressure changes [a]				
	Changes of BP from the Point of Calibration (mmHg)			
SBP	-30 – -15	-15 – 0	0 – 15	15 – 30
DBP	-20 – -10	-10 – 0	0 – 10	10 – 20
Required Samples	13.6% (18)	34.1% (42)	34.1% (42)	13.6% (18)

[a] Blood Pressure change refers to the reference reading measured by the observers minus the value at the calibration point.

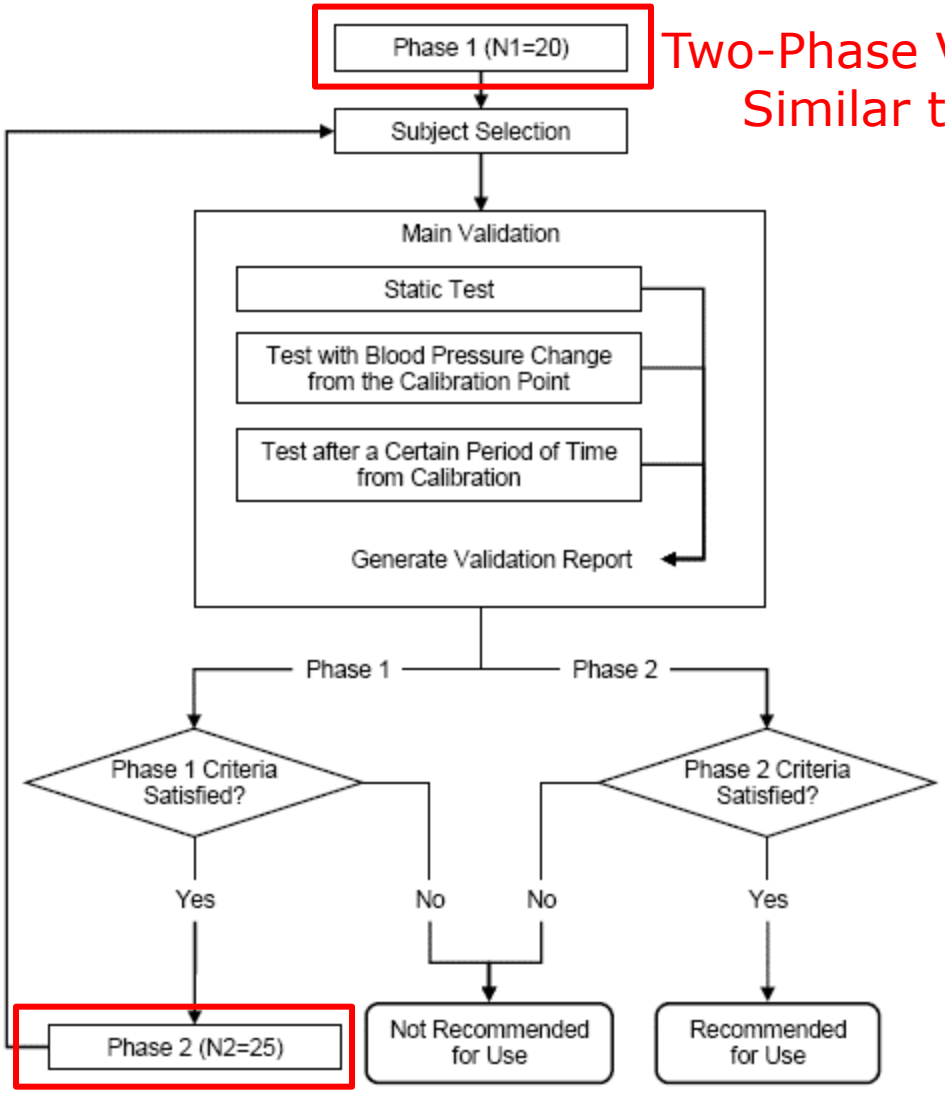
IEEE Std 1708-2014

Cuffless Blood Pressure Standard

- **Observer training and measurement:** 2 observers are trained in accurate BP measurement.
- **Subject selection:** 20 subjects are recruited at Phase 1 of the assessment and an additional 25 subjects are recruited at Phase 2.
- **Main validation:**
  - static test,
  - test with BP change from the calibration point, and
  - test after a certain period of time from calibration.
- **Data analysis:** the collected data are analyzed and compared to the stated accuracy criteria.
- **Data reporting:** The results are presented in recommended format.

IEEE Std 1708-2014

Cuffless Blood Pressure Standard



Two-Phase Validation
Similar to ESH

Thank You!

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