



HEARTS

IN THE AMERICAS Regional Workshop

Punta Cana, Dominican Republic
May 14-17, 2019



PAHO



**World Health
Organization**





HEARTS

IN THE AMERICAS Regional Workshop

Punta Cana, Dominican Republic
May 14-17, 2019



PAHO



**World Health
Organization**



There is a worldwide abundance of BP devices that have not been tested for accuracy (non-validated) or are known to be inaccurate

People unaware

Consequences

Incorrect diagnosis &
treatment decisions

Opportunity lost to perform best-
practice care for CVD prevention



Technical package for cardiovascular disease management in primary health care

Access to essential medicines and technology



Technical package for cardiovascular disease management in primary health care



Evidence-based treatment protocols



Technical package for cardiovascular disease management in primary health care



Team-based care



Technical package for cardiovascular disease management in primary health care



Systems for monitoring



The Lancet Commissions

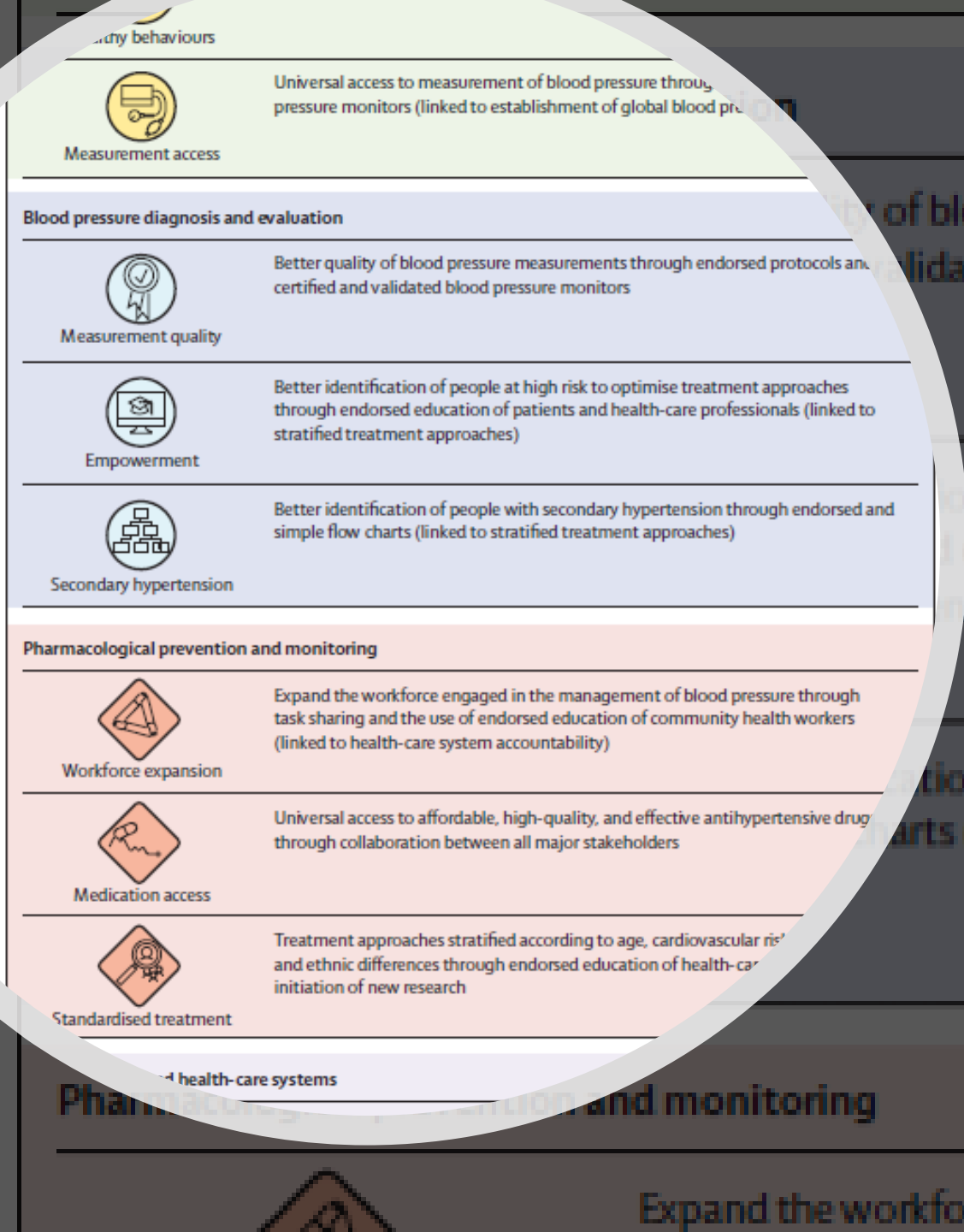
THE LANCET



The mark "CDC" is owned by the US Dept of Health and Human Services and is used with permission. Use of this logo is not an endorsement by HHS or CDC or any particular product, service, or enterprise.

A call to action and a lifecourse strategy to address the global burden of raised blood pressure on current and future generations: the *Lancet* Commission on hypertension

Michael H Olsen, Sonia Y Angell, Samira Asma, Pierre Boutouyrie, Dylan Burger, Julio A Chirinos, Albertino Damasceno, Christian Delles, Anne-Paule Gimenez-Roqueplo, Dagmara Hering, Patricio López-Jaramillo, Fernando Martinez, Vlado Perkovic, Ernst R Rietzschel, Giuseppe Schillaci, Aletta E Schutte, Angelo Scuteri, James E Sharman, Kristian Wachtell, Ji Guang Wang*



10 Key Actions

Expand the workforce engaged in the management of blood pressure through

Blood pressure diagnosis and evaluation



Measurement quality

Better quality of blood pressure measurements through endorsed protocols and certified and validated blood pressure monitors

Lancet Commission on Hypertension Group Position Statement on the Global Improvement of Accuracy Standards for Devices that Measure Blood Pressure

¹James E Sharman, ²Eoin O'Brien, ³Bruce Alpert, ⁴Aletta E Schutte, ⁵Christian Delles, ⁶Michael Hecht Olsen, ⁷Roland Asmar, ⁸Neil Atkins, ^{8A}Eduardo Barbosa, ⁹David Calhoun, ¹⁰Norm RC Campbell, ¹¹John Chalmers, ^{11A}Ivor Benjamin, ¹²Garry Jennings, ¹³Stéphane Laurent, ¹³Pierre Boutouyrie, ¹⁴Patricio Lopez-Jaramillo, ¹⁵Richard J McManus, ¹⁶Anastasia S Mihailidou, ^{16A}Pedro Ordonez, ¹⁷Raj Padwal, ¹⁸Paolo Palatini, ¹⁹Gianfranco Parati, ²⁰Neil Poulter, ²¹Michael K Rakotz, ²²Clive Rosendorff, ²³Francesca Saladini, ²⁴Angelo Scuteri, ²⁵Weimar Sebba Barroso, ²⁶Raymond R. Townsend, ²⁷Ji-Guang Wang, ²⁸Tine Willum Hansen, ²¹Gregory Wozniak and ²⁹George Stergiou, on behalf of the Lancet Commission on Hypertension Group.

The following organisations and institutions endorse this position statement: Lancet Commission on Hypertension Group, American Heart Association, American Medical Association, Artery Society, **Brazilian Society of Cardiology**, British and Irish Hypertension Society, Chinese Hypertension League, Danish Heart Foundation, Danish Society of Hypertension, European Society of Hypertension Working Group on Blood Pressure Monitoring and Cardiovascular Variability, Finnish Hypertension Society, French Society of Hypertension, High Blood Pressure Research Council of Australia, Hypertension Canada, International Society of Vascular Health, **Latin American Society of Hypertension**, National Heart Foundation of Australia, Norwegian Society of Hypertension, **Pan American Health Organisation, Resolve to Save Lives**, Swedish Society of Hypertension, Stroke and Vascular Medicine, **World Hypertension League**.

The Lancet Group is seeking to implement the position statement actions in collaboration with PAHO and partner organisations and members of the HEARTS implementation countries

VALIDATION = EQUIVALENCE



European Society of Hypertension International Protocol revision Validation of blood pressure measuring devices in adults

...N, [Stergiou G](#), [Karpettas N](#), [Parati G](#), [Asmar R](#), [Imai Y](#), [Wang J](#), [Mengden T](#), [Shennar](#)
[Blood Pressure Monitoring of the European Society of Hypertension.](#)

The British Hypertension Society protocol for the re-evaluation of blood pressure measuring devices

Eoin O'Brien*, **James Petrie*†**, **William Littler*‡**,
Michael de Swiet*§, **Paul L. Padfield*¶**, **Douglas G. Altman††**,
Martin Blood††, **Andrew Coats§§** and **Neil Atkins**
(2009)45.

Validation of measuring accuracy. for automatic blood press

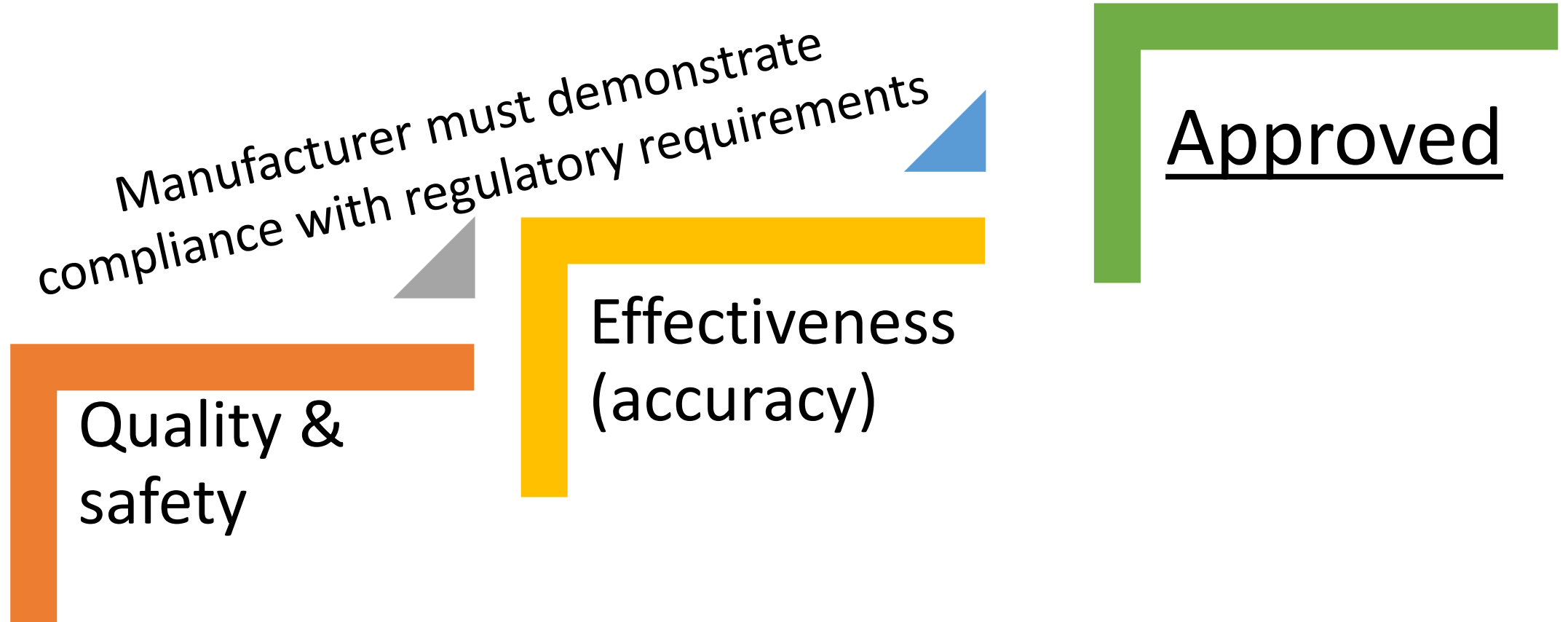
Working Group on Blood Pressure Monitoring of the
European Society of Hypertension International Protocol for
Validation of blood pressure measuring devices in adults

O'Brien^a, Thomas Pickering^b, Roland Asmar^c,
Myers^d, Gianfranco Parati^e, Jan Staessen^f,
Mengden^g, Yutaka Imai^h, Bernard Waeberⁱ and

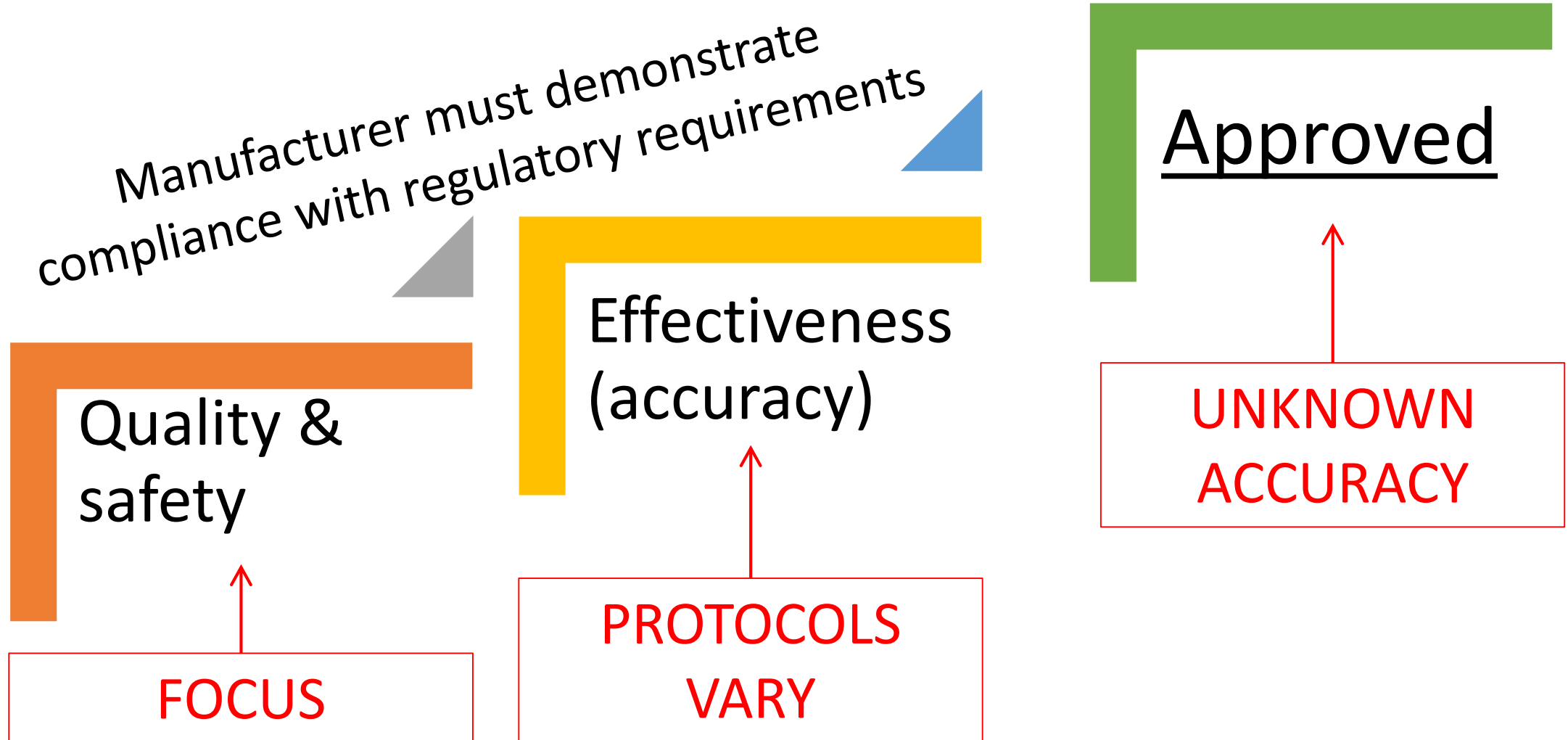
latini^j and with the statistical assistance of Neil Atkins^a
Gerin^k, on behalf of the Working Group on Blood
Monitoring of the European Society of Hypertension

Internationally recognised
validation protocols (can confirm
with online searches; PubMed,
Medaval Registry, Google, Dabl
Educational Trust & more)

How a BP device become approved for sale



How a BP device become approved for sale



Not mandatory for manufacturers to use a specific standard to assess BP device accuracy

BP devices may pass regulatory requirements for sale but fail independent validation of accuracy

Validation studies deviate from established protocols

Consumer organisations do not give due attention to BP device accuracy

Regulatory requirements focus on safety rather than accuracy

Exact BP device used in the validation study is unclear

BP devices may fail to produce accurate readings in people with large or small arms but still used

poor process

bias

confusion

ignorance

misinformation

fraudulence

uncertainty

ambiguity

Not mandatory for validation testing to be performed by independent parties

Assumed that a BP device 'cleared' by regulatory authorities is accurate

Online sale of BP devices may circumvent regulatory processes

Results of BP devices that fail validation studies may not be published

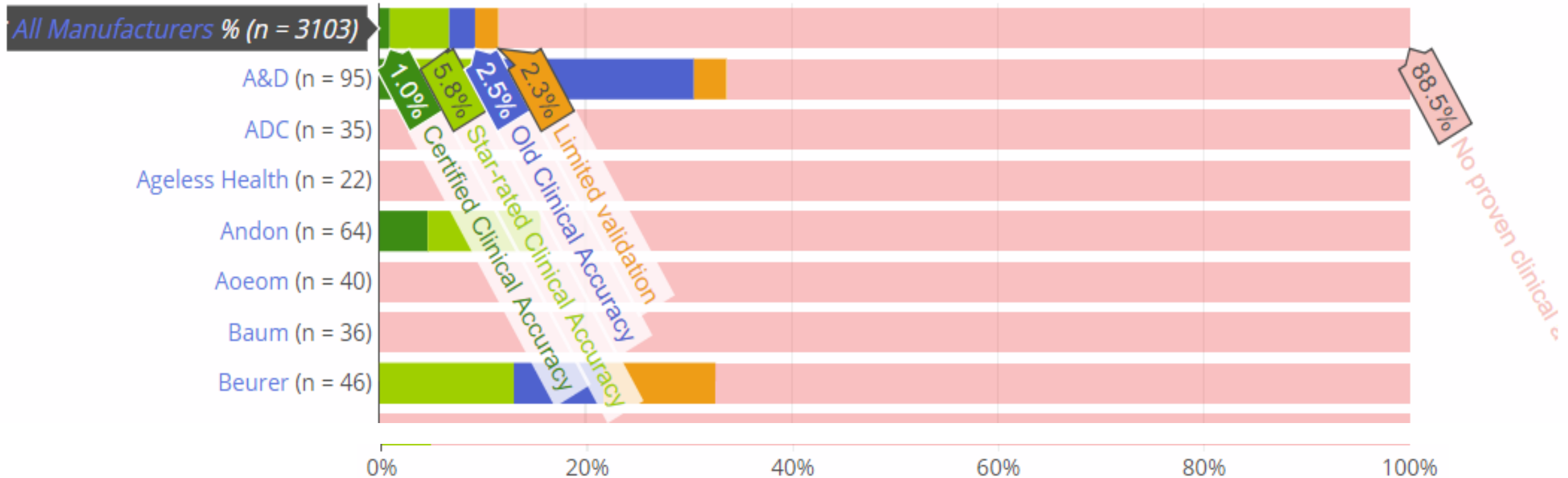
Unethical companies selling cheap BP devices online with false validation credentials



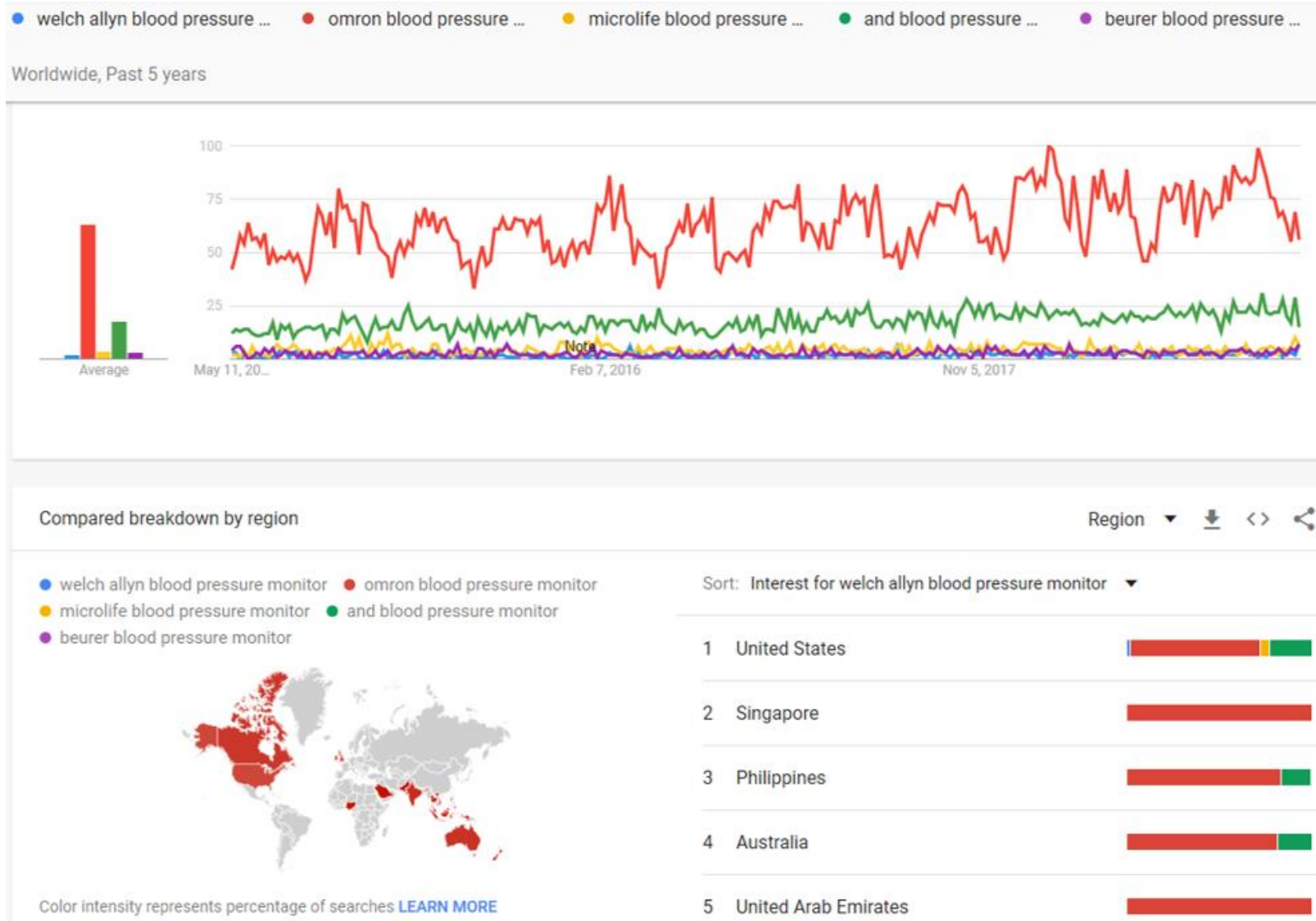
Inaccurate
BP devices

88.5% no proven clinical accuracy

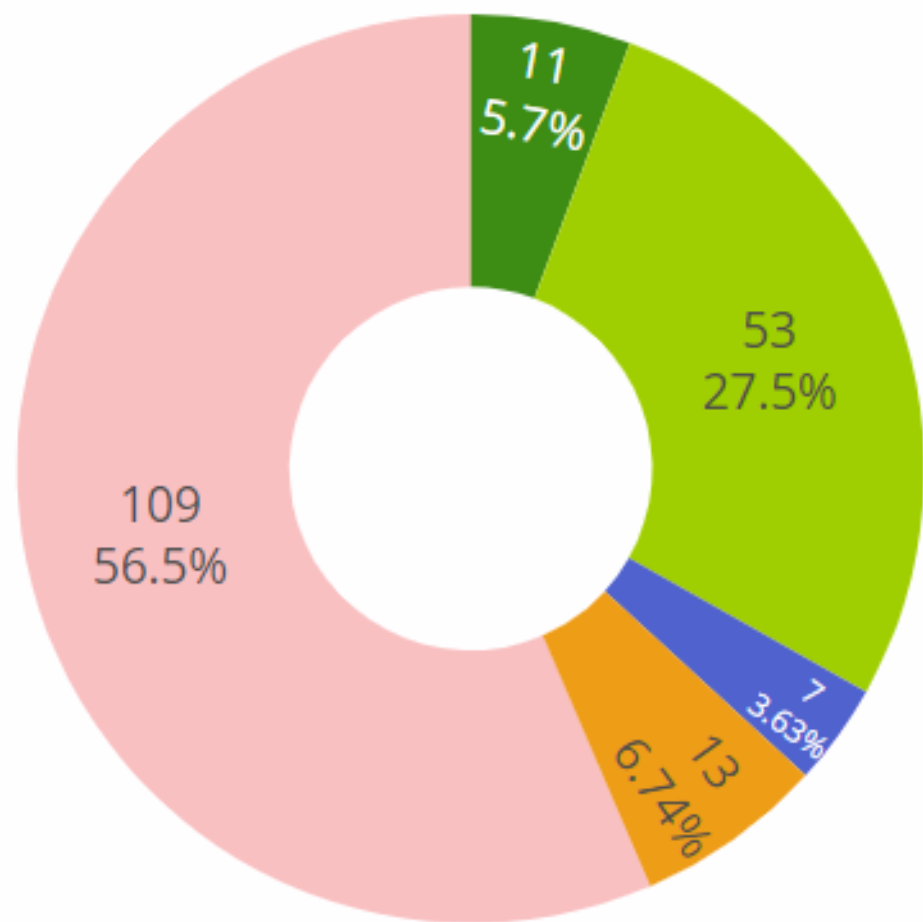
Manufacturers with 20+ BPMs listed on Madaval Percentage of Clinically Accurate Blood Pressure Monitors



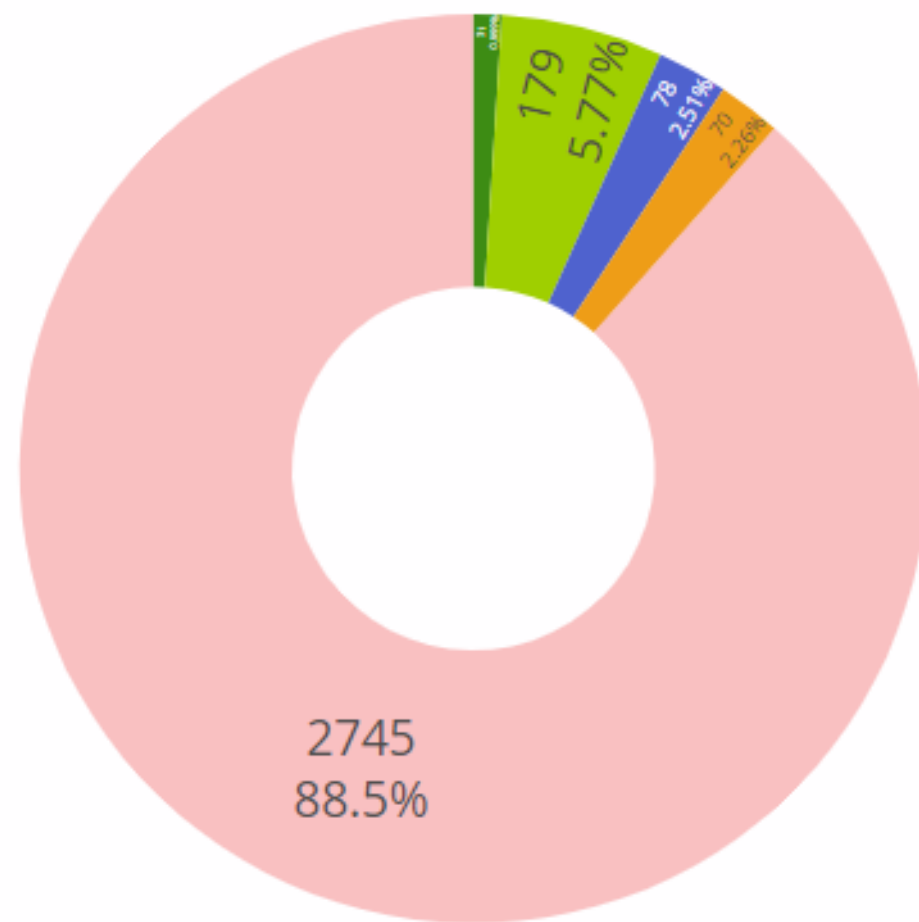
Omron is the most searched BP device company







Omron (n = 193)




All Manufacturers (n = 3103)

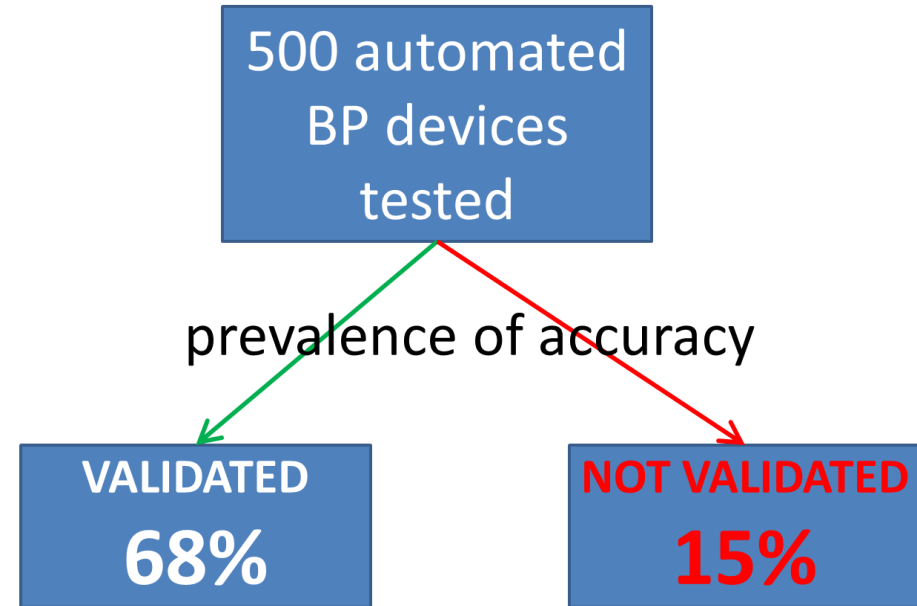


 Certified Clinical Accuracy
 Limited validation

 Star-rated Clinical Accuracy
 No proven clinical accuracy

 Old Clinical Accuracy

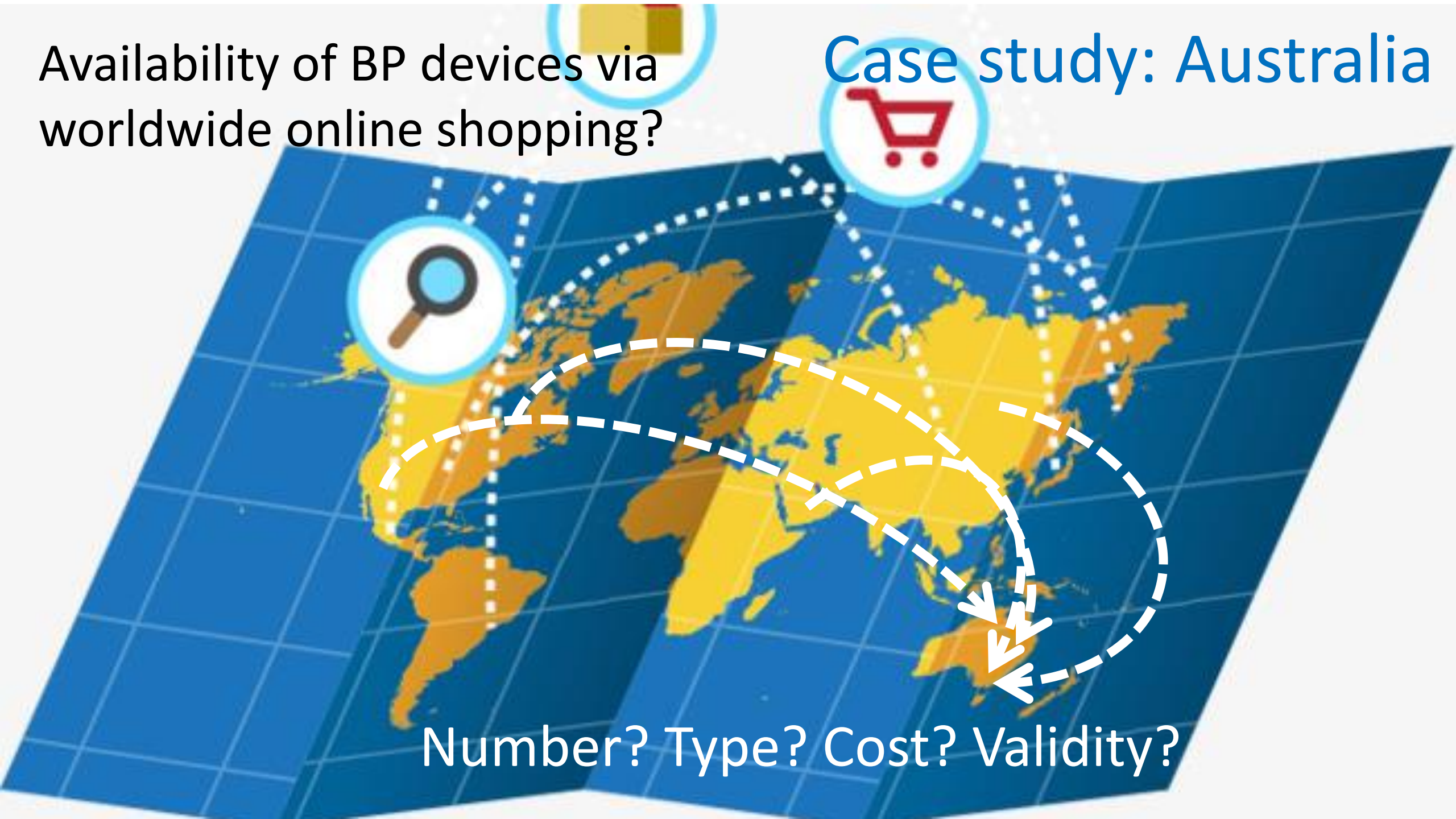
Accuracy versus validation



Akpolat T, Blood Press Mon 2009

Availability of BP devices via worldwide online shopping?

Case study: Australia



Number? Type? Cost? Validity?

Total online retailers

N=59

Pharmacies

n=16

Medical

n=19

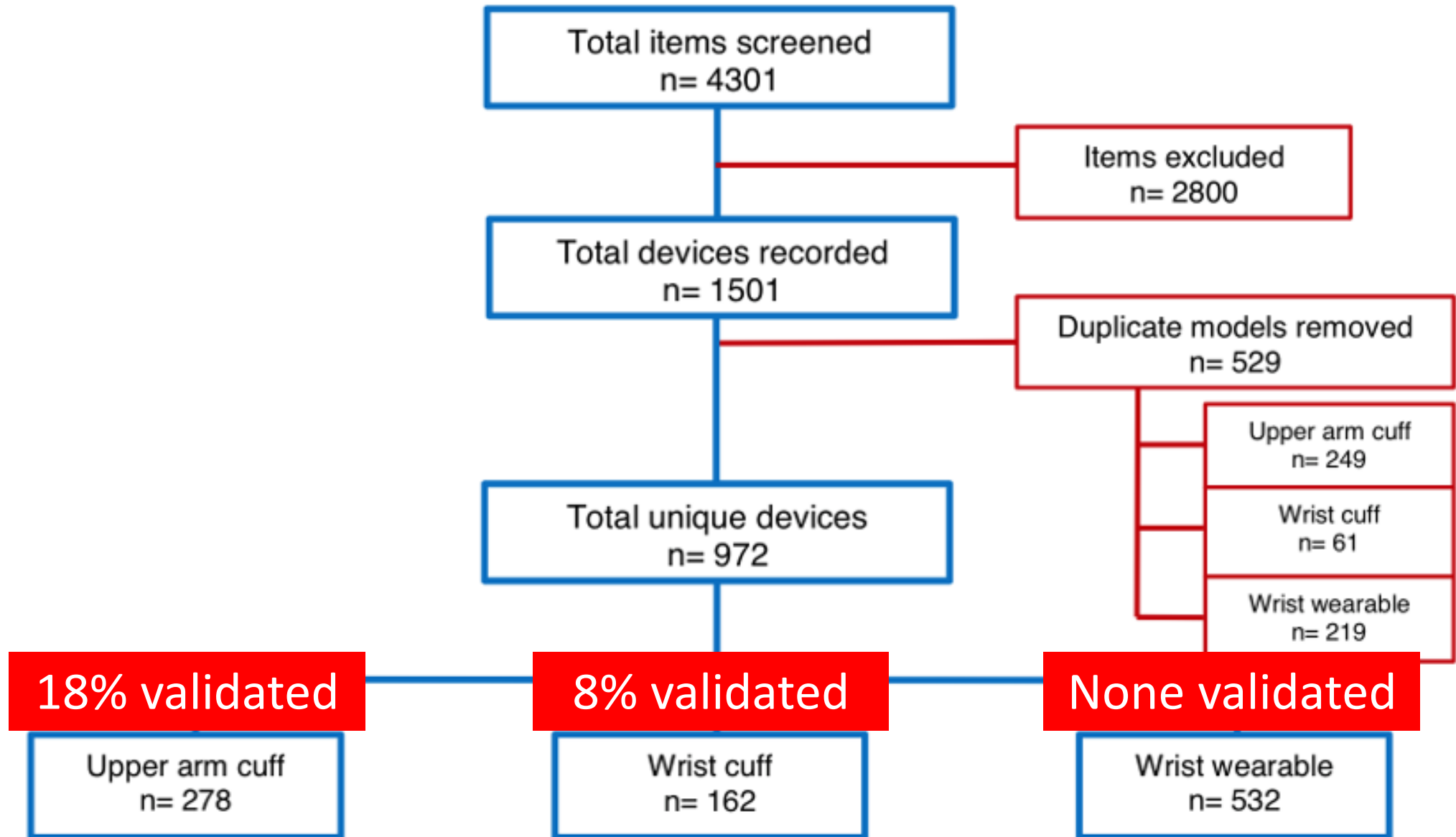
General

n=5

eCommerce

n=19

e.g. Amazon,
eBay.....



50

Loco!

972

Total online retailers

N=59

Pharmacies

n=16

Medical

n=19

General

n=5

eCommerce

n=19

e.g. Amazon,
eBay.....

Supplied 92% of the
BP devices but only
5.5% validated



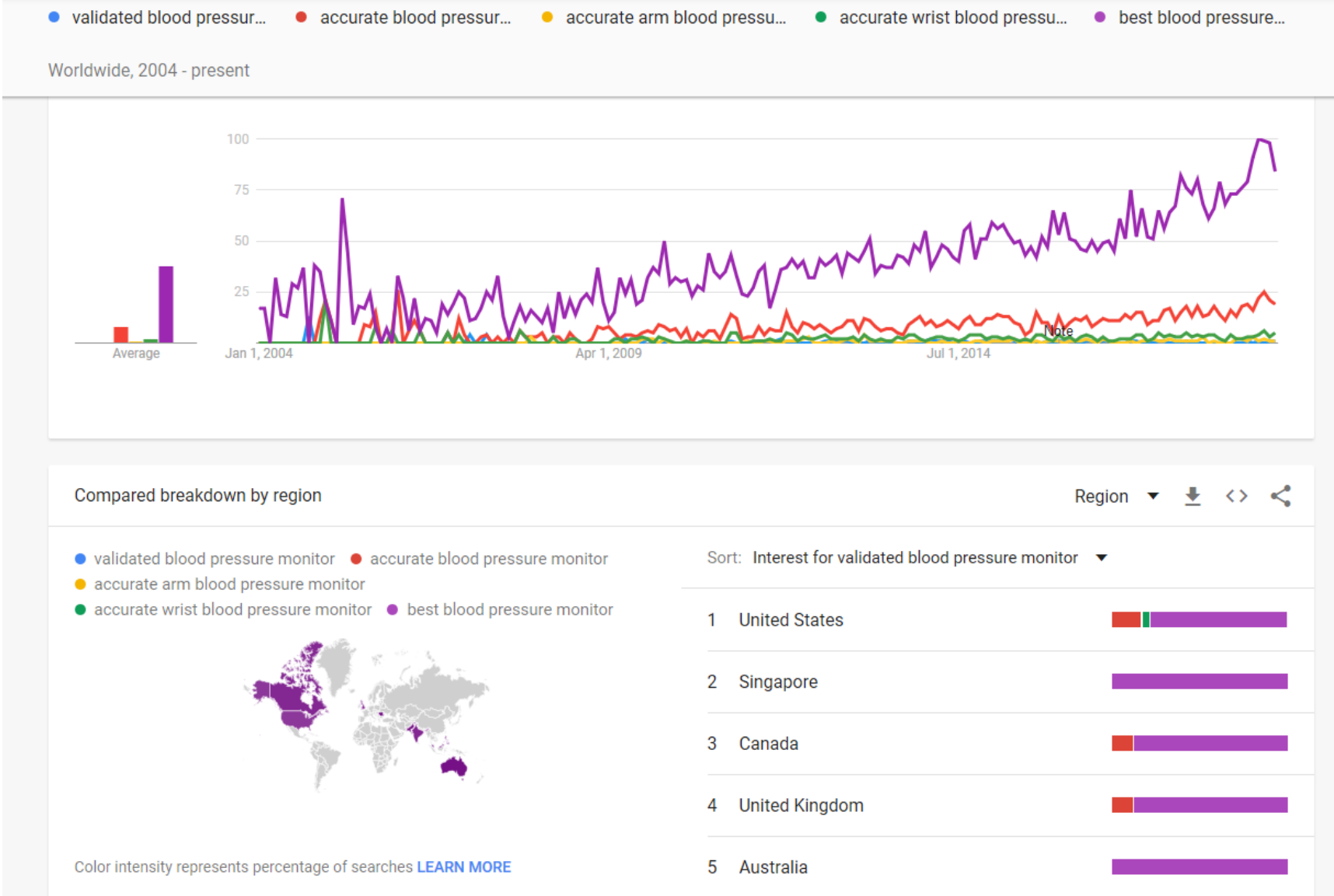
Validated devices cost more than
non-validated devices

\$85.45 (49 – 129 AUD) vs \$50.68 (23 – 95 AUD)



So which devices do people purchase when they look the same, and (apparently) function the same?

“Best blood pressure monitor”





Best blood pressure monitor



- best blood pressure monitor
- best blood pressure monitor **australia**
- best blood pressure monitor **app**
- best blood pressure monitor **watch**
- best blood pressure monitor **2019**
- best blood pressure monitor **au**
- best blood pressure monitor **india**
- best blood pressure monitor **australia 2019**
- best blood pressure monitor **consumer reports**
- best blood pressure monitor **wrist or upper arm**

Google Search

I'm Feeling Lucky

Report inappropriate predictions

There appears to be no peer-reviewed clinical validation information available on the technology used in the Omron HEM-7320 to measure blood pressure.

Accuracy Assessment	Recommendation	Basis
Medaval	Not recommended	This device has not been clinically validated.

Consumer Body	Version	Quartile	Comment
Choice (Australia)	2019	A	This review must not be considered as a substitute for a proper peer-reviewed scientific assessment




- Department**
- Health & Household
 - Blood Pressure Monitors
 - See more
 - Industrial & Scientific
 - Sphygmomanometers
 - Medical Diagnostics & Screening
 - Sports & Fitness
 - Heart Rate Monitors
 - Electronics
 - AC Adapters
 - Electronic Equipment Warranties
 - See All 19 Departments
- Avg. Customer Review**
- ★★★★★ & Up
 - ★★★★☆ & Up
 - ★★★☆☆ & Up
 - ★★☆☆☆ & Up
 - ★☆☆☆☆ & Up
- Brand**
- Omron
 - Care Touch
 - Slight Touch
 - Generation Guard
 - iProven
 - iProven
 - Greater Goods
 - Vive Precision
 - AlphaMed
 - JUNING
 - Health
 - Union
 - Withings
- Electronic Warranty Length**
- 1 Year
 - 2 Year
 - 3 Year
 - 4 Year
 - 5 Year

SPONSORED BY HOMEDICS

Trusted Results In The Comfort Of Your Home

Shop now



Automatic Blood Pressure Monitor, Wrist | Smart Measure Technology | Battery Operat... ★★★★☆ 1

★★★★★ 7 [prime](#)

Upper Arm Blood Pressure Monitor by Veratru - Includes: Fully Auto Monitor, Fit-All Cuff, 4AA & Carrying case - XXL LCD Display, ... by Veratru

★★★★★ - 45

\$27⁹⁹

Eligible for Shipping to Barbados

WARM LIFE Accurate Automatic Upper Arm Blood Pressure Monitor Digital BP Machine Pulse Rate Monitoring Meter with 8.8-14.1i... by WARM LIFE

★★★★☆ - 75

\$29⁹⁹

Eligible for Shipping to Barbados

HoMedics Automatic Blood Pressure Monitor, Wrist | Smart Measure Technology | Battery Powered, One-Touch Operation |... by Homedics

★★★★☆ - 1

\$14⁹⁹ \$26.99

Only 6 left in stock - order soon.

Blood Pressure Monitor Watch, Waterproof Color Screen Fitness Tracker with Heart Rate Blood Oxygen Monitor, Smart... by YZJ

★★★★★ - 31

\$32⁹⁹

Eligible for Shipping to Barbados. In stock on March 17, 2019.

Upper Arm Blood Pressure Monitor by Veratru - Includes: Fully Auto Monitor, Fit-All Cuff, 4AA & Carrying case - XXL LCD Display, ... by Veratru

★★★★☆ - 45

\$27⁹⁹

Eligible for Shipping to Barbados

Blood Pressure Monitor Watch, Waterproof Color Screen Fitness Tracker with Heart Rate Blood Oxygen Monitor, Smart... by YZJ

★★★★★ - 26

\$32⁹⁹

Eligible for Shipping to Barbados. Only 4 left in stock - order soon.





HEARTS

IN THE AMERICAS
Regional Workshop

Blood Pressure Devices: Recommendations From the Lancet Commission on Hypertension Group

Professor James Sharman

Menzies Institute for Medical Research, University of Tasmania

Australia



PAHO



World Health
Organization

