

YOUNG INVESTIGATORS:

Putting the pressure on nonvalidated blood pressure monitors

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In 2016, the Lancet Commission on Hypertension identified ten key actions to improve the management of blood pressure (BP).¹ One of these actions was Measurement Quality, specifically, *better quality of BP measurements through endorsed protocols and certified and validated BP monitors*. Hypertension guidelines invariably recommend that the measurement of BP is performed using monitors that are validated for accuracy. Indeed, this recommendation is classed as essential in the recent International Society of Hypertension guidelines. Accuracy testing should be carried out by independent parties due to conflict of interest on behalf of the manufacturer. Testing should also be according to an internationally-accepted and standardised protocol, where the monitor is compared with reference BP measures.² Unfortunately, due to regulatory loopholes, rigorous accuracy testing may not be performed on many of the BP monitors cleared by regulatory authorities for sale worldwide. This is a problem because non-validated monitors are more likely to be inaccurate³ and thus decisions using BP data from these monitors could lead to mismanagement of BP and sub-optimal clinical outcomes.

Most home BP monitors available for purchase are nonvalidated

To understand the extent of this problem, our team recently examined the availability of validated home BP monitors for purchase online in Australia.⁴ The

findings are a cause for concern because of the 972 unique monitors identified only 7% were validated for accuracy. Validated monitors were more often upper arm cuff devices (18% of 278 devices versus 8% of 162 wrist cuff devices). More than half of the monitors were wristband (activity-tracker style) wearables and none of these were validated. On average, non-validated monitors were significantly less expensive than validated ones.

The results suggest that people looking to buy a BP monitor are inundated with choice and due to the high prevalence of lower cost, nonvalidated monitors and lack of credible information on validation at the point of sale, are probably more likely to purchase one that has not been validated for accuracy. The findings would probably be replicated in other countries because over 90% of the monitors available in Australia were from e-commerce businesses (e.g. Amazon, eBay), which provide shipping to many countries. One of the study limitations was that sales data on purchases of validated versus nonvalidated BP monitors was not available so the number of people using nonvalidated monitors is unknown. Previous studies from countries other than Australia suggest the prevalence of patients using nonvalidated BP monitors may range from 30%⁵ to 70%.³

A practical resource to guide the purchase of validated blood pressure monitors

The study showed nonvalidated monitors dominate the online marketplace. Importantly, there was rarely reliable information at the point of sale about which monitors are clinically validated. To help consumers identify validated BP monitors, we have developed this practical resource which describes all the validated device listings (e.g. STRIDE BP) available globally and how to search them. The tool is designed for use by the general public, health professionals and policy makers to promote the uptake and use of validated BP monitors and is currently being translated to several languages other than English.

Ongoing efforts

Work of the Lancet Commission on Hypertension translational group is ongoing. This includes the development of a consensus statement on procurement of validated BP monitors. Another relatively new group is the Accuracy In Measurement of Blood Pressure (AIM-BP) collaborative, which

has been established to increase awareness of, and advocate for best practice in BP measurement globally. The collaborative aims to identify, summarize, and knowledge translate important resources in the field of BP measurement in a central repository and to propose future work. Further details on AIM-BP can be found here: <https://www.whleague.org/index.php/j-stuff/awareness-and-screening/aim-bp>

In conclusion, nonvalidated BP monitors are highly prevalent and are likely to be more inaccurate than validated ones, potentially leading to mismanagement of BP. A new practical resource has been developed to help consumers use validated device listings to identify validated BP monitors. Ultimately, an increase in the availability of validated BP monitors should lead to improved measurement and management of BP and better health outcomes related to BP globally.

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