R
e and colleagues found that the DINAMAP models 1846-SX and 1846-SX/P (Critikon Corp) systematically skip 14 values of systolic blood pressure, of which some (140 and 160 mm Hg) are critical in the diagnosis and treatment of hypertension. The findings of Rose and colleagues come as no surprise. The DINAMAP 8100 failed to pass validation. Furthermore, to protect their intellectual and commercial interests, most—if not all—manufacturers of blood pressure monitors operate in secrecy. Against current recommendations, they modify the technical specifications and software of devices without notice or fail to subject new or modified devices to independent peer-reviewed validation in a timely manner. Guideline committees have repeatedly demanded that producers submit their algorithms to expert panels, so that the underlying physiological and physical principles can be verified and so that the proprietary software can be checked for accuracy. Too many companies mislead doctors and the general public by marketing nonvalidated devices, which sometimes measure blood pressure at anatomic sites other than the brachial artery, a procedure that is prone to error and far from generally endorsed. Other commercial groups, regardless of validation, sell machines for blood pressure self-measurement through public outlets without providing buyers any proper training or information on the limitations of their use. Instructions for professionals as well as other consumers also should be better standardized; they should include guidelines for calibration and state a guaranteed lifetime of accurate use.

The opinions expressed in this editorial are not necessarily those of the editors or of the American Heart Association.

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References

Editorial Commentary

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antihypertensive drug treatment. Because, so to speak, they will become substitutes for pharmacological treatment, they should adhere to the same quality standards and licensing procedures. Regulatory organizations should guarantee the accuracy of blood pressure–measuring devices, oversee their independent verification and certification, and provide rules for their distribution and use. Such regulations are equally needed for professional and lay consumers and for clinical practice and medical research. Ultimately, a doctor’s or a patient’s perception of cardiovascular risk and consequently the quality and the duration of life of many people rely on the correct assessment of blood pressure, not only in the medical environment but also at home or under ambulatory conditions.

Long-term outcome studies with a design similar to that of the Ambulatory Blood Pressure Monitoring and Treatment of Hypertension (APTH) Trial should firmly establish the advantage of further integrating ambulatory blood pressure monitoring or the self-measurement of blood pressure into the routine care of hypertensive patients. These studies would also provide much-needed information on the long-term cost-effectiveness of these techniques. Because such trials are unlikely to be funded by the pharmaceutical industry, governments, health insurance companies, and above all, manufacturers, should assume responsibility in this regard. It would be of particular interest to hear the opinion of the Food and Drug Administration on these issues.
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