

Standards for blood pressure measuring devices

In 1985 the British Hypertension Society established a working party on blood pressure measurement to make recommendations on the technique of measurement, and the recommendations have now been published.^{1,2} The working party was also asked to improve the accuracy of measuring devices and examine the feasibility of providing minimal standards for all such devices. The introduction and enforcement of such standards are urgently needed because semiautomated devices of unproved accuracy are proliferating to cater for the increasing market for self measurement of blood pressure. Technically complex and extremely expensive semiautomated devices for operating theatres and intensive care areas have also been successfully marketed, often without independent validation. Ambulatory blood pressure measuring systems are increasingly in demand as well and are not only costly but also are often exorbitantly expensive to operate and maintain.

As a first step the working party set out to determine what standards, if any, existed in other countries and how manufacturers were made to comply with such standards.³ None of the European countries approached appears to have effective standards, and those standards that do exist are out of date.^{4,6} In Britain, Ireland, and most of Europe the validation of automated and semiautomated blood pressure measuring devices depends on independent researchers with an interest in blood pressure measurement.^{7,9} The British Standards Institution is reviewing its standards for mercury and aneroid sphygmomanometers, and recently the biomedical engineering group of the Committee for Medical Research of the European Community approved a project to coordinate research on ambulatory monitoring, which is to include assessing the prognostic value of ambulatory blood pressure recording in patients with hypertension.¹⁰ This project will inevitably call for an appraisal of devices used for the non-invasive assessment of ambulatory blood pressure. Recently the Australian Standards Committee has drafted

stringent proposals to improve standards,^{11,12} and comprehensive standards for blood pressure measuring equipment have been operating for several years in the United States.¹³⁻¹⁸ With advances in technology, however, even these standards are now outdated, and the Association for the Advancement of Medical Instrumentation has recently revised the standards for mercury and aneroid sphygmomanometers¹⁹ and is now finalising its recommendations for automated devices.²⁰

Having ascertained policy elsewhere, the working party recommends that the existing standards^{4,5} for mercury and aneroid sphygmomanometers should be revised without delay. It also proposes to draw up comprehensive standards on the accuracy, efficiency, and safety of semiautomated and automated devices and to consider their cost—not only to buy but also to maintain.

But how can standards be enforced? Clearly neither the British Hypertension Society nor any other body can validate all blood pressure measuring devices on the market. The only practical solution is to make manufacturers produce evidence that they have complied with the standards. Though standards may eventually be enforced by legislation,²¹ the British Hypertension Society proposes to ask bodies such as the Department of Health and Social Security, the Scottish Home and Health Department, the British Standards Institute, the Medical Research Council, the Department of Health in Ireland, the British and Irish Heart Foundations, and the British and Irish Cardiac Societies to recommend purchase only of blood pressure measuring equipment that satisfies the standards. A regulatory procedure will be needed to process applications from manufacturers for approval of equipment, and facilities will have to be created to provide at least random assessment and validation of new devices. The British Hypertension Society, perhaps in association with the British Standards Institute, could designate and support one or more laboratories like this in Britain and Ireland.

In the meantime, what recommendations can be made to

those thinking of buying blood pressure measuring equipment? Firstly, the mercury sphygmomanometer is the most accurate, reliable, durable, and economical of all devices for measuring blood pressure.²² Secondly, semiautomated and automated devices should not be purchased unless the manufacturers provide independent validation of accuracy preferably published in a reputable journal.

Several major companies have behaved responsibly in assuring that their products are accurate, reliable, and value for money, but there are many products on the market (and the number is increasing) that are inadequately tested and sold at considerable profit. Some marketing strategies rely on an independent laboratory taking five years to produce verification and accuracy studies. Medical journals are often reluctant to publish such technical evaluations, and at least another five years may pass before enough published evidence accumulates to harm sales. The British Hypertension Society is determined to reverse this trend.

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