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**FOR IMMEDIATE RELEASE**

**STEPS NEEDED TO ENSURE THAT HOME MEDICAL DEVICES ARE EASY-TO-USE AND CAREGIVERS ARE WELL-TRAINED**

WASHINGTON – A new [report](http://www.nap.edu/catalog.php?record_id=13149) ([http://www.nap.edu/catalog.php?record\\_id=13149](http://www.nap.edu/catalog.php?record_id=13149)) from the National Research Council recommends steps the Food and Drug Administration and other agencies and professional associations can take to ensure that the medical devices and health information technology used in home health care are easy and safe for laypeople to use and that caregivers, whether formal or informal, are well-trained.

For many reasons -- including the rising cost of health care, the aging of the U.S. population, and patients' desire to remain in their homes -- health care is increasingly moving from formal medical facilities into homes. A wide range of procedures, therapies, and monitoring tasks are now carried out far from any hospital or clinic, often with no health care professional on-site. So far, however, little attention has been paid to ensuring that this transition of care into the home happens safely and effectively.

The report recommends that FDA promote the development of new standards for labels on medical devices intended for use in the home, as well as for the accompanying instructional materials, to ensure that they are understandable to nonprofessionals. Standards and guidance for labeling these devices are currently lacking.

FDA also should make it easier for people to report problems with medical devices they use in the home; its current systems for reporting adverse events are not easy for laypeople to use. In addition to making these systems user-friendly, the agency should collect more data that could help identify the root causes of adverse events involving devices and should develop and promote a more convenient way for lay users and professionals to report problems.

In addition, FDA and the Office of the National Coordinator for Health Information Technology should work together to regulate, certify, and monitor applications that integrate medical devices and health information technologies -- for example, devices that monitor patients' blood pressure and provide results to patients and their doctors. The Office of the National Coordinator for Health Information Technology should also work with other agencies to establish guidelines and standards for making consumer health information technologies usable and accessible.

The way home caregivers are trained needs to be improved, the report adds. Professional practice and advocacy groups should develop certification, credentialing, and training standards that will prepare formal caregivers to practice in the home. They should develop informational and training materials for informal caregivers as well.

The report recommends that the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, and other federal agencies collaborate to facilitate adequate access to health- and safety-related home modifications, especially for those who cannot afford them, enabling people whose homes contain safety hazards or obstacles that limit self-care to obtain the modifications they need.

The study was sponsored by the Agency for Healthcare Research and Quality. The National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council make up the National Academies. They are private, nonprofit institutions that provide science, technology, and health policy advice under a congressional charter. The Research Council is the principal operating agency of the National Academy of Sciences and the National Academy of Engineering. For more information, visit <http://national-academies.org>. A committee roster follows.

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Pre-publication copies of [Health Care Comes Home: The Human Factors](#) are available from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242 or on the Internet at <http://www.nap.edu>. Reporters may obtain a copy from the Office of News and Public Information (contacts listed above).

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