

Ensuring Medical Devices are Reliable



Staff from the Regional Medical Physics Department, are funded by the Department of Health, via the Medicines and Healthcare products Regulatory Agency (MHRA) to provide a valuable service for the whole of the NHS. They assess the performance of certain types of medical device (defibrillators, patient monitors, blood pressure monitors and audiometers) to help NHS staff make informed purchasing decisions. The group also provides a region-wide calibration service for hearing test equipment in hospitals, health centres, GP surgeries and educational establishments that is complementary to the evaluation service.

External cardiac defibrillators

Defibrillators are commonplace in hospitals and ambulances, and are now being made available in public places, such as airports, railway stations and shopping centres. Evaluation work focuses on assessing the performance of automated external defibrillators (AEDs) which can detect lethal heart rhythms and are intended for use by minimally-trained operators. Adverse incidents, where devices fail to operate as expected, can occur throughout the NHS, and an additional role of the group is to conduct incident investigations.

Blood pressure devices

Traditional mercury sphygmomanometers used for blood pressure measurement are being phased out for environmental reasons, and in many cases are being replaced by automated (self-measurement) blood pressure devices. There is evidence that automated devices may be inaccurate in some circumstances, and the group is leading a pilot study to investigate the problem.

Patient monitors

Patient monitors are used in every NHS hospital, especially in critical care. Evaluations have a particular emphasis on new technologies, and their relevance to the NHS.

Audiometer evaluation and calibration

National initiatives in digital hearing aid dispensing and hearing screening for new-born babies have created demand for specialist hearing test equipment. The evaluation programme assesses

the performance of such equipment, and feedback from the regional audiometer calibration programme has helped with recommendations for screening audiometers for community use.

Publications

Results of evaluation assessments are published by the Department of Health in the Evaluation series of reports, which are free to the NHS, and are distributed to all NHS hospital libraries, supplies officers and medical engineering departments. In addition, the group at Freeman is leading a project to publish evaluation information on-line via the NHS net. The site can be found at <http://www.evaluation.nhs.uk>.

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