Cardiovascular Computer Devices: Balancing Novelty, Flexibility, Familiarity and Safety

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Without cardiovascular devices the success of modern medicine would be poorer and many lives now saved would be lost. Many devices now rely on computers, either in their standard recognisable format, or hidden in devices ready to run at the push of a button and without any need to load or start a program. This invasion by computing into cardiology has brought with it many advantages. Diagnoses and treatments not possible several years ago are now indispensible. The ability to introduce novelty, user flexibility and diversity, as well the clear presentation of results has reaped many advantages.

Nevertheless, computers have brought with them problems, many of which have a direct bearing on patient safety. In the UK the National Patient Safety Agency collates all reports of medical safety incidents in the UK, and the Medicines and Healthcare products Regulatory Agency (MHRA) deals with incidents specifically involving medical devices. Most other countries have similar bodies. In their latest report the MHRA indicated that there had been over 8000 UK device incidents in the previous year, of which over 1000 involved a serious injury and over 200 a death. Of the total incidents, 12% were life support and 3% imaging.

Specific computer problems can relate to the device not behaving as planned in the design, either because the device was not correctly programmed, or unexpected conditions appeared, or because of external interference or other influences. Also, clinical staff can often use devices in unintended ways, either because the functions were not clear, or because staff became lost in the many layers of user interaction. Versatility is not always a positive feature. There is much that can be learnt, either as a clinical user, developer or manufacturer of cardiovascular computer devices by reviewing safe design.