



- Title** Patient's Bedside Biological Analyzer
- Agency** CEDIT, Committee for Evaluation and Diffusion of Innovative Technologies
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- Reference** CEDIT Report (in French) 98.04/Ra3/01/Recommendation 98.04/Re3/01.

Aim

The CEDIT was consulted in April 1998 by the Director General of AP-HP on the benefit for the institution of delocalized biochemical analyzers placed near the patient's bed.

Results

The speed in obtaining high-quality results with this type of device is confirmed. Delocalized biology near the patient is seen to enable real-time treatment of patients in outpatient or day-hospital settings.

This device, which is time-consuming for healthcare professionals, should be compared to a system for the rapid transfer of samples (pneumatics, etc). Its installation requires the establishment of a quality control system where the biologist writes down procedures and validates them, monitors and controls disfunctionalities, and trains users.

Recommendations

The CEDIT is of the opinion that widespread use of the device in hospitals must be limited to emergency services, intensive care units, and operating rooms which do not always have the option to rapidly transfer biological samples. The installation and choice of a patient bedside device must be submitted to a competent commission consisting of biologists, prescribing clinicians, a nursing representative, a biomedical engineer, and a hospital management representative.

Methods

A multidisciplinary working group formed by the CEDIT in 1998 gave an opinion on the validity of the technical performances of the main device involved (i-STAT[®]), on its conditions of use, and on the degree of use of this type of device within AP-HP.

The working group then recommended supplementary studies to evaluate the practical effects of such a bedside biological analyzer in AP-HP hospitals once a primary study had verified the device's reliability.

After the technical results were validated, a protocol was set up in the emergency room of the Louis-Mourier hospital (Colombes – France) to analyze the practical effects of biological analyzers at the patient's bedside. This was a single-center, longitudinal study comparing 2 months of activity: May 1999, when the assays were still conducted in customary biochemical laboratory conditions (242 patients included) and May 2000, when the iSTAT[®] system became available along with the customary method (293 patients included).