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the end of the target temperature time, could be useful as prognostic factors of in-hospital mortality.

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T125

Impact of the COVID-19 crisis on the Point-of-Care blood gases management in an ISO 22870 accredited laboratory in Paris (France)

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Background-aim

Our laboratory is accredited for Point-of-Care (POC) blood gases activities according to the ISO 22870 standard. When, in March 2020, the Covid-19 crisis hit France, risk assessment was done to adapt POC management to the setting up of 3 new dedicated Covid-19 intensive care units.

Methods

We used our change management procedure based on risk assessment management (CLSI EP-23) and prioritization of risks (criticality scale) to reveal new risks to take into account:

- Material: - Insufficient number of blood gases devices. - Shortage of reagents requiring anticipating the potential peak of analysis (units full of ventilated patients).
- Manpower: - Newly trained-empowered people recruited for the Covid-19 crisis requiring to derogate from the usual training procedure to increase the rate of operational users. - Staffing shortage in the clinical units or in the laboratory due to illness.
- Methods: - Reduced initial analyzer performance check for quick commissioning. - Necessity of indicators to monitor the impact of derogations to usual procedures and to verify the adequacy with the clinician's needs.
- Environment: - Potential impact of SARS-CoV-2 on analyzers management (device contamination, waste, protection of users).

Results

Material: One GEM 4000 was put back into service and 2 additional GEM 5000 (Werfen) were ordered and put into service the day of reception 9 days later. Reagent orders were tripled to avoid shortage due to potential future manufacturer's deficiency. Eventually, POC blood gases activity increased + 300% at the peak of the crisis in April without any particular problem. Manpower: 35 new users were trained-empowered with a quick-training procedure. A punctual lack of trained user never happened and daily monitoring of rejected analysis (new indicator) showed even better results than expected. Methods: Indicators allowed to verify that specific requirements of ISO 22870 were still achieved. Environment: No special procedure was required for the analyzer itself aside the general procedure for COVID-19 clinical unit management.

Conclusions

Our change management procedure allowed our ISO 22870 accredited laboratory to add these new locations/POC analyzers to our scope of accreditation during the peak of the COVID-19 crisis.

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T126

Prospective comparison of point-of-care INR versus plasma INR in supra-therapeutic INR values

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Background-aim

Point-of-care testing (POCT or bedside testing) provides faster results than those obtained in hospital laboratory analyzers, but it should not compromise quality and safety. Compared to arterial and venous blood, capillary blood can easily be collected from the fingertip and does not require a skilled worker. Therefore, it has excellent potential as an ideal blood source for disease diagnosis and health monitoring. In coagulation, these systems are very useful for obtaining the INR test to monitor vitamin K antagonist (VKA) oral anticoagulant therapy. Xprecia XtrideTM(Siemens®) is a POC system with an ergonomic design, touch screen and intuitive software that, after performing an automatic calibration and two quality control checks on each test strip, provides the INR from analyzing a 6 l sample of capillary blood, reporting data between 0.8 and 8. It uses Innovin® reagent with ISI 1. Protocol dictates that a POC device should be assessed for reproducibility against a central laboratory analyzer since INR is essential for proper oral anticoagulation management. Regarding the NCCLS guidelines, there is an statistical equivalence of INRs obtained from POC systems - within 0.4 for a target INR of 2.5 and within 0.7 for a target INR of 3.5. Generally, results with an INR exceeding 5.0 have reduced trueness, precision, and linearity, both in POC and laboratory-based testing.

Aims: Is this a comparative study of INRs obtained using a POC system (POC-INR) compared to INRs obtained using plasma from venous samples collected in citrate tubes (P-INR), both taken from the same patient at the same time. In previous studies undertaken at our hospital, we found linearity between both methods and no statistically significant differences. In this study, our intention was to demonstrate if such a correlation existed exclusively in supra-therapeutic INR results.

Methods

POC-INR was obtained from a capillary sample analyzed with POC Xprecia XtrideTM(Siemens®). If the INR was above 3.0, a venous citrated sample was taken and a P-INR was obtained from an ACL-TOP500 hospital analyzer (Werfen®), using the reagent Hemosil Recombiplastin® ISI 1. The results were compared with the Medcalc statistical package to calculate the Pearson correlation coefficient and non-parametric Passing-Bablok regression analysis, suitable for method comparison studies.

Results

We took 215 POC-INR samples that were higher than 3.0, and also took P-INR from the same patients at the same time. A correlation coefficient of r = 0.7698 with a 95% confidence interval (0.7091 to 0.8192) was obtained, with the regression equation y = 0.160 + 0.967 X, where...