Background-aim

When the Biochemistry department on the Wythenshawe site of Manchester University NHS Foundation Trust first achieved ISO 15189 laboratory accreditation in 2016, this was a big step towards extending the standards to our POCT program. Wythenshawe achieved 22870 accreditation in September 2018, making the department only the second NHS trust to be awarded POCT accreditation in the UK. Based on interest from peer institutions, we propose a roadmap for achieving ISO 22870, using our blood gas testing program as an example.

Methods

Wythenshawe is a 900-bed teaching hospital providing acute care services to adult and paediatric patients. POCT service includes more than 300 devices—29 blood gas analysers, 180 hand-held glucose, ketone, tHb and chemistry devices— equating over 2million individual patient tests each year.

Achieving ISO 22870 involved the efforts of the POCT team, clinical teams, learning and development, the main laboratory and our supplier partners to establish: e-learning, a Quality Management System (QMS), define Key Performance Indicators (KPI), and audit for improvement opportunities.

The blood gas testing service at Wythenshawe includes 29 GEM® Premier™ 5000 with iQM2® (Instrumentation Laboratory) analysers interfaced into GEMweb® Plus which is a key element to the POCT program.

Results

The efforts performed for the blood gas testing can be used as a model for other institutions to achieve ISO 22870:

1. Build e-learning program – standardised analyser platform with Operator Competency modules in GEMweb Plus
2. Establish standardised documentation within the QMS system – Maintenance-free analysers simplify staff-time, documentation and elevate quality
3. Identify KPIs for POCT dashboard – built-in KPIs and iQM2 risk-management features facilitate monitoring for continuous improvement
4. Set up monitoring process – sample handling reports in GEMweb Plus enable monitoring for operator training

Conclusions

Seeking accreditation aligns with the Wythenshawe objectives to grow our clinical expertise and expand our research programs. Being awarded ISO 22870 validated the quality of our comprehensive POCT service. The built-in features of the GEM Premier 5000 with iQM2 and GEMweb Plus not only facilitated ISO quality requirements automatically, but also helped free up POCT staff to focus on the broader framework of the overall accreditation program.

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M364

Evaluating the clinical risk of biotin interference with the Elecsys® Troponin T-high sensitive assay

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Background-aim

The biotin-streptavidin-based Elecsys® Troponin T-high sensitive (cTnT-hs) assay (Roche Diagnostics) has a high negative predictive value for ruling out acute myocardial infarction (AMI), but biotin >20 μg/L can reduce recovery by >10%. We assessed the risk of patient misclassification due to biotin interference.

Methods

Biotin was measured in two cohorts using an Elecsys® biotin assay. The acute coronary syndrome (ACS) cohort comprised 797 initial (0-hr) and 646 3-hr blood samples from 850 patients with suspected AMI in the US. The US laboratory cohort comprised 2023 random samples from a US laboratory network; biotin concentrations were extrapolated for higher values using pharmacokinetic data to simulate future use of high-dose biotin for multiple sclerosis. Prevalence of biotin >20 μg/L and 99th percentile biotin were calculated, and the impact of elevated biotin on cTnT-hs was modelled in both cohorts. In the US laboratory cohort, the misclassification risk was determined using global (excluding US) 14 ng/L and US 19 ng/L cTnT-hs cutoffs, and for a biotin washout time of 3 hrs based on pharmacokinetic data.

Results

ACS cohort: one (0.13%; 30.23 μg/L) initial and one (0.15%; 24.48 μg/L) 3-hr sample had biotin >20 μg/L; 99th percentile biotin was 2.62 μg/L (initial) and 2.38 μg/L (3-hr), >7 times lower than the assay interference threshold. US laboratory cohort: 15 (0.74%) samples had biotin >20 μg/L; 99th percentile biotin was 16.62 μg/L. Using conservative assumptions in the ACS cohort (including tripling the highest observed biotin concentration per CLSI EP07 guidelines), biotin interference could lead to a falsely low value for an initial cTnT-hs result between 19 and 45.24 ng/L; the likelihood of false-negative AMI prediction was 0.026% at 0 hrs. Using extrapolated biotin data from the US laboratory cohort, the misclassification risk due to biotin interference using 14 ng/L and 19 ng/L cTnT-hs cutoffs, respectively, was: 0.025% and 0.026% at 0 hrs; 0.00049% and 0.00048% at 3 hrs.

Conclusions

In our study, biotin interference had a minimal impact on cTnT-hs diagnostic performance and the risk of false-negative AMI prediction due to biotin was low.

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M365

Real-time monitoring of drug-laboratory test interactions with an automated decision support application

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Background-aim

The lack of knowledge of the presence of Drug-Laboratory Test Interactions (DLTIs) can cause misinterpretation of laboratory test results and delayed or erroneous diagnosis with extra healthcare costs and even harm to patients. There are over 50.000 physiological and/or analytical drug-test interactions described. In this pilot study, an automated decision support application was used to detect drug laboratory test interactions in real-time.

Methods

In this multicentre study, 34 clinical rules about DLTI were programmed and validated in an automated decision support application (Gaston, Medecs B.V.). The DLTIs were described in a validated database from the Dutch Society for Clinical Chemistry. The application is able to generate a DLTI-based advisory text based on predefined aberrant laboratory test results and medication data from individual patients and present this alert text to the laboratory specialist in the laboratory information system. The software application was successfully connected and installed in one hospital laboratory in 2018 with two other hospitals to follow in 2019. Generated real-time DLTI alerts were collected and monitored during 4 weeks.

Results

A mean of 45 DLTI alerts were generated per day. Twenty-one out of 34 clinical rules were generated at least once in this period. The most frequently reported interactions were magnesium - proton pump inhibitors (14%), creatine kinase – statins (13%) and potassium - ACE-inhibitors (13%). Most DLTI alerts were from the internal medicine department (43%), cardiology department (22%) and the emergency department (10%).

Conclusions

In this study, an automated decision support application was implemented to facilitate signalling the presence of drug laboratory test interactions. A mean of 45 DLTI alerts per day were generated in this study. The clinical relevance of the alerts for laboratory specialists and physicians will be examined.

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