K52 Exemplification of Continuous Quality Improvement by Quality Surveillance: Laboratory Incidents and Corrective/ Preventive Approaches

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After attending this presentation, attendees will be acquainted with examples of laboratory incidents that could be used as a basis to improve performance of a laboratory by taking incidence-driven corrective/preventive measures.

This presentation will impact the forensic community and/or humanity by exemplifying incidents that are commonly encountered in a laboratory. Upon the rectification of those incidents by taking appropriate corrective/preventive measures, the overall performance of a laboratory would be improved. Monitoring of laboratory incidents is a realistic and simple approach for quality surveillance, thereby for continuous quality improvement.

The Federal Aviation Administration's Civil Aerospace Medical Institute (CAMI) conducts toxicological evaluation of postmortem biological samples collected from victims involved in fatal civil aircraft accidents. The submitted samples are analyzed for the presence of primary combustion gases, alcohol/volatiles, and drugs. Throughout the entire evaluation process, a high degree of quality control/quality assurance (QC/QA) is maintained, and continuous quality improvement is always administratively sought.

Under this philosophy, as quality surveillance, an "Incident Reporting" module was instituted in the CAMI Toxicology Database in October of 2000. Any member of the CAMI Laboratory was allowed to report an incident, but it was evaluated by designated QC/QA scientists on an incident-by-incident basis. This process involved (i) categorization of types and severity of incidents, (ii) best-educated estimates of dollar amounts and labor hours ($20.00/hour) associated with the incidents, and (iii) corrective/preventive measures taken in response to those events. Incidents with a labor hour of <
0.5 were not included. To evaluate effects of the reporting on the laboratory performance, the Toxicology Database was searched for incidents that were reported during 2000–2004. Associated dollar amounts/labor hours and types/severity of incidents were retrieved from the Database. Information related to the corrective/preventive actions taken to rectify the incidentrelated deficiencies was also collected.

These findings revealed that incident types pertained to accessioning, analytical, clerical, procedural, report generation, security, and other deficiencies. Severity of incidents, categorized as major, moderate, minor, and undefined, varied from analytical-batch rejection to typographical, to power outage. Corrective/preventive approaches included proofreading, counseling, and repeating tasks. This aspect also included implementing modified or new procedures and providing training to the laboratory members. Taking these quality approaches reduced the number of incidents from 61 in 2001 to 8 in 2004, thereby reducing the laboratory cost from $4,400 in 2001 to $730 in 2004. The decrease in labor-cost hours was consistent with the decrease in the incidents and dollar cost. Clerical errors were the highest in number, followed by analytical and accessioning. Although incident severity was highly prevalent in 2001, the overall severity decreased during ensuing years. Major incidents were associated with analysis, followed by accessioning, which is consistent with the very nature of postmortem forensic toxicology since these are essential components of a toxicology laboratory. Based upon the incident reporting, corrective/preventive measures—such as peer review, proofreading, procedure modification, and new method implementation—were undertaken. Training through mentorship, attending workshops/ meetings/symposia, and taking courses was also provided to the laboratory members. These approaches led to a decrease in incidents during the period, 2002–2004. For example, there was a drastic decrease in clerical errors—no such incidents were significant enough to warrant corrective measures after 2002. Average completion time per case decreased from 46 days in 2003 (199 cases) to 35 days in 2004 (180 cases) for positive cases and from 37 days in 2003 (283 cases) to 31 days in 2004 (269 cases) for negative cases, indicating a tendency in the decrease in case completion time.

Findings from this study suggested that the quality surveillance improved product quality, saved time and money, streamlined and implemented procedures, thus enhanced the overall performance of the laboratory. The "Incident Reporting" will continue to be an effective and important aspect for improving quality of laboratories.

Toxicology, Laboratory Incidents, Continuous Quality Improvement

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