eQA

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Quality Indicators (QIs) in Laboratory Medicine

Quality indicators (QIs) are fundamental tools for enabling users to assess the quality of all operational processes by comparing it against a defined criterion. The identification of reliable QIs in Laboratory Medicine is a crucial step in enabling clinical users to quantify the quality of laboratory services. The laboratory should establish QIs for systematically monitoring and evaluating the laboratory's contribution to patient care. The current lack of harmonization of the potential QIs and reporting systems associated with laboratory testing have made it difficult to apply QIs as part of a coherent and integrated quality improvement strategy. QIs data should be collected over time to identify, correct, and continuously monitor defects and improve performance and patient safety by identifying and implementing effective interventions [1, 2].

According to the last version of the international standard for clinical laboratory accreditation (ISO 15189: 2012, clause 4.14.7 Quality indicators), *"The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes"*. However, there is no consensus or recommendations focusing on the adoption of universal QIs and common terminology in the total testing process. A preliminary agreement has been achieved in a Consensus Conference organized in Padua in 2013, after revising the model of quality indicators (MQI) developed by the Working Group (WG) on "Laboratory Errors and Patient Safety" of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). The consensually accepted list of QIs, which takes into consideration both their importance and applicability, should be tested by all potentially interested clinical laboratories to identify further steps in the harmonization project all over the world.

Points to note [3]:

1. Quality indicators (QIs) are fundamental tools for improving laboratory services.
2. QIs should address all stages of the Total Testing Process (TTP).
3. The model of QIs developed by the IFCC-WG covers all steps of the testing process.
4. Currently available quality indicators and reporting systems should be harmonized.

Key Quality Indicators [4]:

1. *Patient/Specimen Identification. May be any of the following: percent of patient wristbands with errors, percent of ordered tests with patient identification errors, or percent of results with identification errors.*
2. *Test Order Accuracy. Percent of test orders correctly entered into a laboratory computer.*
3. *Stat Test Turnaround Time. May be collection-to-reporting turnaround time or receipt-in-laboratory-to-reporting turnaround time of tests ordered with a "stat" priority. May be confined to the Emergency Department or intensive care unit if a suitable reference database is available. Laboratories may monitor mean or median turnaround time or the percent of specimens with turnaround time that falls within an established limit.*
4. *Critical Value Reporting. Percent of critical results with documentation that results have been reported to caregivers; percent of critical results for which the primary clinician cannot be contacted in a reasonable period of time.*
5. *Customer Satisfaction. Must use a standardized satisfaction survey tool with a reference database of physician or nurse respondents.*
6. *Specimen Acceptability. Percent of general hematology and/or chemistry specimens accepted for testing.*
7. *Corrected Reports – General Laboratory. Percent of reports that are corrected.*
8. *Corrected Reports – Anatomic Pathology. Percent of reports that are corrected.*
9. *Surgical Pathology/Cytology Specimen Labeling. Percent of requisitions or specimen containers with one or more errors of pre-defined type.*

10. *Blood Component Wastage. Percentage of red blood cell units or other blood components that are not transfused to patients and not returned to the blood component supplier for credit or reissue.*
11. *Blood Culture Contamination. Percent of blood cultures that grow bacteria that are highly likely to represent contaminants.*

Assessing the quality of laboratory services using QIs or performance measures requires a systematic, transparent, and consistent approach to collecting and analyzing data. A comprehensive approach would address all stages of the laboratory TTP [5, 6]. The QI chart (Table 1 of ref. 7) developed by IFCC LEPS “Laboratory Errors and Patient Safety” (WG LEPS), was presented as a means of harmonizing measurement of TTP. The list contains a comprehensive series of QIs, covering all steps of the TTP, that have been considered to be applicable to all laboratories despite their complexity, technological level, and need of close interaction with clinicians and other healthcare staff [7].

Current efforts in China (ref. 8, 9 in simplified Chinese characters):

“为加强医疗质量管理与控制，完善我国医疗质量管理与控制指标体系，规范医疗机构和医务人员执业行为，保障人民群众身体健康和生命安全，依据卫生部办公厅关于委托制订临床实验室质量管理与控制指标体系函[卫办医政函〔2009〕723 号]的精神，卫生部临床检验中心已组织有关专家，根据美国病理学家学会(CAP)的质量探索（Q-Probes）和质量跟踪（Q-Tracks）计划中所制定和监测的质量指标、美国临床和实验室标准化研究院（ CLSI）有关文件、我国《医院管理评价指南》（卫医发〔2008〕27 号）、《综合医院评价标准》（2009 年版）、《患者安全目标》（2010 年版）及《医疗机构临床实验室管理办法》（卫医发[2006]73 号）中对临床实验室质量和管理的规定要求，并结合我国的

基本国情来制定了如下的临床实验室质量管理与控制指标。

按照分析过程的不同阶段，可将制定的临床实验室质量指标分为分析前、分析中和分析后的质量指标。在各个分析阶段中，又着眼于可能对实验室报告结果有影响的关键步骤将指标再细分。目前提出的质量指标有分析前 20 项，分析中 11 项，分析后 29 项，共 60 项。各阶段具体指标如下 …" [8]：

Source: http://www.nccl.org.cn/webnotice/?type=detail&id=29

2015 年 4 月 13 日，国家卫生计生委网站发布了临床检验专业质控指标（2015 年版）。包括标本采集运送、检验周转时间、室内质控、室间质评、危急值报告等 15 条质量控制指标。这是首次以专科为单位，系统地发布医疗质控指标，为卫生行政部门和医疗机构加强医疗质量管理提供了工具 [9]。

Source: http://www.nhfpc.gov.cn/ewebeditor/uploadfile/2015/04/20150415094156987.pdf

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