

Clinical Governance and Evidence Based Laboratory Medicine

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Clinical Governance, "a framework through which the NHS organizations are accountable to continue to improve the quality of the service and safeguarding high standards of care by creating an environment in which excellence in clinical care would flourish", is aimed to improve the overall standard of clinical care, ensuring that clinical decisions are based on the most up to date evidence in terms of effectiveness.

The Clinical Governance principles seem to be of value in healthcare system worldwide in terms of quality, effectiveness and accountability. In Italy, these principles are at the base of the health care reform that has the goal to promote the effectiveness and appropriateness of the use of health services.

Clinical Effectiveness, a vital part of Clinical Governance, is a term that refers to measuring and monitoring the quality of care and also comprises various activities that include: Evidence Based Practice, Research & Development, Clinical Audit, Clinical Guidelines, Integrated Care Pathways, Total Quality Management. Clinical effectiveness are based on the best available research evidence, as assessed by meta-analyses and systematic reviews and made more understandable and operational, in the case of diagnostic process in Laboratory Medicine, by the use of expressions as likelihood ratios, area under the ROC curve, sensitivity and specificity. The best available research evidence are usually derived from clinically relevant research,

often from the basic sciences of medicine, but especially from patient centred clinical research into the accuracy and precision of diagnostic tests, the power of prognostic markers, and the efficacy and safety of the diagnostic intervention or consequent treatment. New evidences from clinical research both invalidate previously accepted diagnostic tests and procedures and replace them with new ones that are judged more powerful, more accurate, more efficacious, and safer.

The application of EBM in Laboratory Medicine or Evidence Based Laboratory Medicine (EBLM) aims to advance clinical diagnosis by researching and disseminating new knowledge, combining methods from clinical epidemiology, statistics and social science with the traditional pathophysiologic molecular approach. EBLM, by evaluating the role of diagnostic investigations in clinical decision-making process, can help in translating the results of good quality research into every day practice.

Clinical Guidelines EBLM oriented are pivotal in training and maintaining performance in a Clinical Governance policy because they center the attention on the efficacy to support the decision-making process required in good clinical practice, in this view both the introduction of a new diagnostic procedure or the currently traditional routine activities should be subject to a regular audit practice to evaluate the quality and appropriateness of care in Laboratory Medicine.