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External quality assessment of hormone determinations

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Hormone determinations are of central importance to the practice of Clinical Endocrinology, and ensuring their correct use and performance is a multidisciplinary responsibility involving clinicians, laboratory staff, manufacturers of diagnostic systems and healthcare regulatory agencies. All these professional groups have, therefore, an interest in external quality assessment (EQA) as an audit tool that can identify areas where use of tests in routine practice requires improvement to reduce risks to patients.

This chapter reviews the principles of EQA, and outlines its strengths and limitations, illustrated with example data from the UK National External Quality Assessment Service (UK NEQAS). The immunological nature of many hormone assays, often further complicated by heterogeneity of analyte structure and lack of suitable calibrators, presents special problems for the designers of EQA schemes in ensuring that specimens are appropriate and that target values are accurate.

Laboratory users of EQA should have sufficient knowledge of the characteristics of the EQA schemes in which they participate to make informed interpretation of their data. The trend since the 1980s for in-house assays designed in individual laboratories to be superseded by automated assays provided by a small number of diagnostics manufacturers places a special responsibility on manufacturers to ensure reliable assay design and calibration. In collaboration with other parties EQA can help identify priorities for improved assay design and calibration.

Although traditionally the focus of EQA has been on assessing the analytical phase it can also make some assessment of other important aspects of performance, e.g. the consistency of reference ranges and how results are interpreted.

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Overall, EQA has a valuable role both in laboratory accreditation and as an educational resource, thereby helping to ensure and improve the quality of laboratory services that support patient care.

Introduction

Laboratory test results contribute significantly to diagnostic decision-making, particularly in endocrinology, where their appropriate use is of key importance to delivering the best clinical outcomes for patients and enabling efficient use of health care resources. In practice, this means that the correct test(s) should be selected, the correct specimen taken from the correct patient at the correct time, the analysis performed using an accurate and reliable method, and the results interpreted appropriately. Together, these steps are a shared responsibility requiring multidisciplinary input (Fig. 1). Clearly the infrastructure and management of hospitals and health centres will vary in different countries. Regional and national policies, including arrangements for laboratory accreditation and clinical governance, shape and influence the laboratory service provided for all tests, including endocrine analytes. These broad strategic issues are critically important but are beyond the scope of this chapter, which will focus on how external quality assessment can serve as an audit tool to ensure and improve the quality of laboratory testing in clinical endocrinology.

From its inception [1], EQA has focussed on the technical aspects of the analysis, but with changes in laboratory practice and increasing awareness that errors can occur in all stages of laboratory testing – from pre-analytical, through analytical to post analytical (Table 1) – the focus of EQA and related audit has broadened to address wider aspects of investigative testing. EQA of the analytical phase remains the core activity of EQA, however, although even here the focus of interest has changed over time, as in-house and manual immunoassays have been superseded by automated assays using reagent kits. The end user has limited control over these, and the onus of responsibility for analytical quality has shifted substantially towards the providers of automated analysers. All these changes have implications for providers of EQA schemes, participating laboratories, accreditation agencies and clinicians who use laboratory services.

In this chapter the design and operation of EQA of the analytical stage is described, and how EQA and other audit surveys can be extended to assess the pre-analytical and post-analytical stages

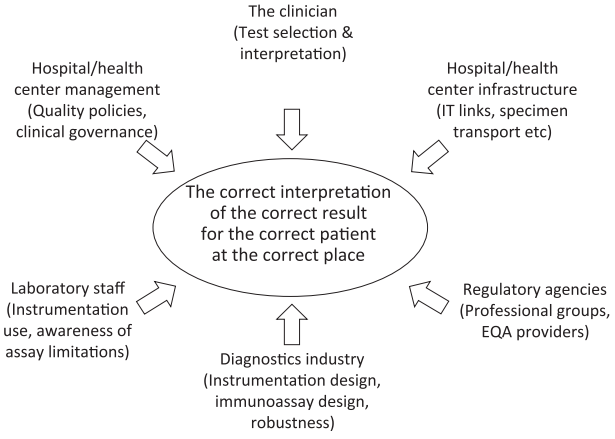

Fig. 1. Parties contributing to the effective use of endocrine tests in clinical care.