

A Tale of Two Pathologists: Questions on Good Laboratory Practice

Two pathologists (A and B) meet with the Head of Department to discuss the establishment of a new molecular biology-based clinical test, which would be used to help in the diagnosis and management of a particular cancer.

Pathologist A had done some work on the assay in another lab and has experience in using this test as a clinical diagnostic tool. However, Pathologist B is apprehensive and would like to see a proper clinical validation of the test performed at this facility before it is launched as a clinical test.

Appropriate laboratory data are essential for clinicians to accurately assess the status of patients' health, make accurate diagnoses, formulate treatment plans, and subsequently monitor the effects of treatment. The clinician must be able to trust the test results from the laboratory in order to use them for clinical diagnosis and treatment. Currently the clinical utility of the test for interpretation of results and subsequent patient management is under study in many other laboratories.

Pathologist A explains that he plans to establish the test using a standard protocol used by other labs abroad. This, he says, is required since the test is not performed using a commercial kit since none have been developed for it so far. Each lab starting the test must therefore develop its own protocol based on standard guidelines to establish a sensitive, standardised assay. This, he assures the Head of the Department, is the standard practice for any "in-house" clinical test like this one as opposed to commercial tests that have already undergone extensive validation and screening prior to launch in the market. Pathologist A mentions that patient samples will therefore be required for establishing the assay in the lab.

Pathologist B comments that since they do not know whether the test in question will meet the validation requirements or not, the process for establishment

and validation falls under the realm of research and therefore should be written up as a proper study and submitted to the Institutional Review Board (IRB) like any research proposal. She further states that this assessment will only be possible if the process is clearly defined as a research study where the objective will be to evaluate all the relevant parameters that could affect the end result. Since the preliminary tests to be carried out are investigational, they would not be reported as lab results and should not be paid for by the patient. Furthermore, patients will need to be asked for their consent to participate in the research before their samples can be used for this assay.

Pathologist A maintains that based on his own work elsewhere, this is a proven diagnostic method and needs no further research. Testing for local values, levels and parameters is a normal procedure done with other established processes and does not constitute research. He points out that the test in question was set up at a centre where he was involved and that it included the actual clinical testing of patient specimens. He feels that the results of this activity are enough proof of validity.

Natasha Nabi Anwar