H23 Analytical Test Method Selection and Validation of Laboratory-Based Methods

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After attending this presentation, attendees will have a better understanding of the principles of selecting a method for inclusion in their laboratory's standard operating procedures (SOP) and the necessary steps to validate a laboratory-based method, which may include modifications of longstanding methods.

This presentation will impact the forensic science community by illustrating the principle, spirit, and intent of method validation through the use of a case study-validation of the Hefner Optimized Summed Scoring Attributes (OSSA) method for ancestry determination.

Forensic anthropology laboratories must weigh numerous factors when determining which analytical test methods to include in their SOPs. What is generally accepted as a valid method (*sensu Frye*) by the expert community influences the decision. Further, appropriate weight must be given to adherence to the principles set forth by the *Daubert*, and later, the *Kumo* rulings, which inform the forensic science community on what is admissible to the courts as expert witness testimony and within forensic reports. These rulings stipulate the need for an assessment of a method's relevance, reliability, and, in the case of *Daubert,* the "scientific knowledge" base from which it is developed. Legal requirements, as well as the sentiments developed out of these rulings, certainly have influenced how accrediting bodies recommend best practice and the perceived requirements for minimum standards of a test method. However, the expert community must still vet new and old methods alike to ensure they adhere to these guiding principles. Perhaps more importantly, these methods must also evolve alongside our understanding of the "scientific knowledge" base from which the tests derive *and* the policy-oriented realm in which they will be presented.

Under ISO 17025, the standard used by a testing laboratory to select an analytical method must include considerations of such issues as the needs of the customer, and whether the test is "appropriate." Preferred methods are those published in international, regional, or national standards. Since there are no national (or otherwise) standards in place for forensic anthropological tests, we must move to other tier-utilizing tests published by technical organizations. Also, analytical methods published in relevant scientific texts or journals, or those based on manufacturer's specifications (e.g., scanning electron microscope analysis) serve as *de facto* standards.

Forensic anthropology as a field has certainly taken up the call to ensure the methods used in day-to-day casework meet a *Daubert* challenge. A plethora of validation studies and subsequent modifications to longstanding methods have been presented. Still, not all methods that are published in scientific journals are created equal, and just because a method is published does not make it reliable, valid, or appropriate for the problem at hand. Thus, an additional source for methods which may be selected for inclusion in an SOP is laboratory-developed or adopted methods. This source is acceptable provided the method is appropriate and validated. The validation need only be as extensive as necessary to confirm the procedure fits its intended use; which is a point that could lead to rigorous debate. Confirmation comes from determining the performance characteristics of the intended method.

The Hefner OSSA method was initially developed as part of a doctoral dissertation born from the statistical quantification of the long-used morphoscopic gestalt. The method was then qualified as a laboratory-developed method. As such, it was subject to a planned validation study prior to being accepted into an SOP. Validation could have taken several forms, as will be discussed; however, ultimately the method was tested on an independent sample of American White (n=79) and American Black (n=49) individuals from the William M. Bass Donated Skeletal Collection. After applying the OSSA method, which requires scoring six cranial nonmetric traits according to published protocols, a systematic assessment of the uncertainty involved in the test results was undertaken. Based on the validation study results, performance indicators point to the efficacy of the Hefner OSSA method (sensitivity=87.76%, specificity=89.87%, correct classification rate=89.06%, error rate=10.94%, positive predictive value=84.31%, and negative predictive value=92.26%; in this example, the positive predictive value (true positive/(true positive + false positive)) is the probability the individual is "Black" when OSSA indicates "Black"). The validation of OSSA is ideal to illuminate a discussion of the principle, spirit, and intent of method validation and selection.

Method Validation, Accreditation, Ancestry Determination

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