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THE BENEFITS OF DIGITAL PATHOLOGY IN THE ASSESSMENT OF HER2 ISH IN A NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEME.

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Introduction/ Background

In situ hybridization (ISH) techniques, colorimetric (CISH) and fluorescence (FISH) have been widely applied in breast cancer and are valuable in confirming HER2 gene amplification status as a valid predictor of response to anti-HER2 therapies. UK NEQAS is a well-established multinational scheme for assessing the quality of laboratories performing HER2 ISH testing. Three years ago the UK NEQAS module for HER2 ISH testing moved from using cell lines to human breast cancer tissue samples to assess the interpretive accuracy and technical quality of laboratories performing HER2 testing by ISH. At this time UK NEQAS also began to provide participants with access to digital scans of haematoxylin and eosin (H&E) stained tissue samples to facilitate interpretation of the ISH-stained preparations.

Aims

The objective was to evaluate the use of digital and telepathology in a National External Quality Assessment Scheme.

Methods

Up to 450 pre-labelled glass slides are sent to the HER2 ISH module tissue provider by UK NEQAS, 4 times per annum. The tissue provider selects a range of previously assessed breast cancer cases from their archives and mini tissue microarrays (TMA) are constructed consisting of 4 cases of breast carcinoma representing a range of HER2 ISH scores. During TMA block sectioning, every 25th slide is set aside for H&E staining and digital scanning. All unstained slides are returned to UK NEQAS by the tissue provider for distribution to the more than 200 international participants enrolled in the HER2 ISH module. To assist participants in the assessment of the HER2-ISH stained tissue sample they are provided with a web link to a digital pathology database (Philips Digital Solutions) where they can view the H&E-stained slide corresponding to their ISH-stained slide. The participants return the HER2-ISH stained slide to UK NEQAS for assessment and input the scores obtained for each of the four samples on an online database. The objectives of the HER2 ISH assessment are (1) to evaluate the accuracy of HER2 ISH interpretation by analyzing the inter-observer variability in enumerating HER2, Cep17 counts and overall ratio scores and (2) to assess the quality of the ISH-stained section.

Results

Due to the large number of participants enrolled in the UK NEQAS HER2 ISH scheme, it is not possible to provide each laboratory with a H&E-stained slide. Without a reference H&E-stained slide it can be difficult to clearly identify invasive tumour cells on an ISH-stained preparation increasing the chance of error in the assessment of HER2 gene status in tissue samples. However, with the technological advancement of digital pathology, it has been possible to provide UK NEQAS participants with a relevant H&E-stained slide of the tissue samples. In ***Conclusion,*** digital pathology has greatly facilitated the move from cell lines to breast cancer tissue samples for the UK NEQAS HER2 ISH module. Access to the digitized H&E-stained slides has enabled participants to quickly and more accurately visualize and pinpoint areas of invasive tumour. Our experience confirms the significant role for this electronic resource in EQA, education and continuing professional development.