Revolutionising Retinal Imaging

The rise of AI in ophthalmic practice follows a steep trajectory.

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Artificial intelligence-based algorithms offer the prospect of improved efficiency in delivering care and reduced cost, but translating that potential into clinical practice will require a colossal effort, said Professor Marion R Munk.

"You see a lot of hurdles, but nonetheless AI will definitely make its way into our clinic—and already has. And as always, great revolutions need some time," she said.

The past few decades have seen growing interest and research in artificial intelligence in medicine. A search on PubMed shows only one article on the subject in 1996, compared to more than 22,700 at present. There has likewise been substantial investment in the field with the EU contributing 1.5 billion through 2020 and France alone contributing a further 22,700 published articles, up from almost nothing in the 1990s.

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Moreover, there has been a corresponding explosion in the number of medical AI algorithms and machine learning-enabled devices gaining FDA clearance for clinical use. While most are in fields such as radiology and cardiology, there are also a few cleared for use in ophthalmic diagnostics, such as the LumineticsCore (formerly known as IDx-DR) for diabetic retinopathy screening and the EyeArt (Eyenuk)—previously approved for age-related macular degeneration (AMD) and now approved for diabetic retinopathy screening.

Quantity and quality

Prof Munk noted since the European Medicines Agency's guidelines are less strict than the US FDA's, there are currently more algorithms and AI-enabled ophthalmic devices available for clinical use in Europe than the US. The FDA requires companies submitting AI and AI-enabled devices to always use independent prospective data for the training and testing stages to ensure the data from these cohorts will not overlap. In contrast, the EMA allows the use of retrospective data, which greatly reduces the expense and amount of work involved.

The prediction accuracy of an AI algorithm always depends directly on the quantity and quality of the data used, she said. To create an AI algorithm that can distinguish between the presence, absence, and severity of proliferative and non-proliferative diabetic retinopathy requires around 50,000 to 60,000 images. In addition, for maximum performance, 4.5 graders are needed to label each one. Validating the algorithm

requires a separate, though smaller, set of images likewise labelled by a similar number of graders. The gold standard for FDA approval is a sensitivity of 0.85 and a specificity of 0.825.

Another challenge is ensuring devices from different manufacturers are properly trained on the algorithms. It will also be essential to ensure using the AI devices will not complicate clinician workflow. The desired return from AI technology, she added, is improved efficiency in delivering care and reduced cost. Those benefits have yet to be proven. An additional question is how AI-enhanced diagnostic services will be remunerated—particularly in the EU, where, unlike the US, there are no general billing codes.

Prof Munk spoke during an EURETINA educational webinar, "AI-Based Developments in Retinal Imaging".

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