Artificial intelligence deployment in diabetic retinopathy: the last step of the translation continuum

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See Articles page e235

The disproportionate burden of diabetes worldwide on low-income and middle-income countries (LMICs) is a predicament keenly felt in the field of ophthalmology.[1] Globally, the prevalence of visual impairment due to diabetic retinopathy is rising,[2] attributed to growing rates of diabetic macular oedema, which is now more common than the historically more feared proliferative diabetic retinopathy and is the predominant cause of moderate or severe vision loss in patients with diabetes.[3] Blindness from diabetic retinopathy is rendered all the more poignant by well established data about its preventability with early detection and intervention.[4] Remarkable progress has been made in the application of big data to diabetic retinopathy screening.[5–7] Given the anticipated deficit of already strained resources, automation of screening for high-risk populations using deep-learning systems is appealing because of its potential to effect large-scale implementation at lower cost, if appropriately integrated into clinical practice.

The study by Paisan Ruamviboonsuk and colleagues,[8] published in *The Lancet Digital Health*, reports one such example of clinical deep-learning system deployment. The authors describe the performance of a previously validated deep-learning system in multiple primary care sites across Thailand,[5] integrated for the first time for point-of-care, real-time use as part of Thailand's national diabetic retinopathy screening programme. The primary clinical endpoint of the study was the identification of vision-threatening diabetic retinopathy, encompassing severe non-proliferative diabetic retinopathy, proliferative diabetic retinopathy, or diabetic macular oedema. Compared with local retina specialist over-readers, the deep-learning system had higher sensitivity (91·4% [95% CI 87·1–95·0] *vs* 84·8% [79·4–90·0]; p=0·01), and similar specificity (95·4% [94·1–96·7] *vs* 95·5% [94·1–96·7]; p=0·98) on a per-patient level, with the reference standard adjudicated by a panel of three US board-certified retina specialists.

Although the data supports the robustness of the deep-learning system in diabetic retinopathy screening, the more valuable insights of this work relate to the feasibility and effect of artificial intelligence on delivery of care. However, the study leaves behind important unanswered questions. First, the advantages of artificial intelligence—such as higher referral adherence from real-time point-of-care screening recommendations, more efficient resource allocation due to the deep-learning system offloading tasks from human graders, and increased objectivity in determining ungradable images by the deep-learning system compared with health-care professionals operating under time constraints—are implied but unproven. Quantifying these inferences through formal cost-benefit and post-hoc analyses would help to elucidate the scope of effect that a successful deep-learning system could have and provide a more powerful impetus to motivate change to existing standards of care.

Second, even if the aforementioned benefits of artificial intelligence were shown to be true, the specific workflow proposed for live implementation is not defined and potentially restricted by current practices. For example, if cost-benefit analyses favoured a semi-automated approach using existing graders in the Thai national screening programme (who are not retina specialists), the specificity of the study (which uses retina specialists as secondary graders) might be compromised. Even if a deep-learning system generated increased screenings and better referral adherence, access to subsequent specialty care might be unavailable within the current health-care infrastructure of an LMIC. The ultimate success of an end-to-end deep-learning system does not rest with the accuracy of the deep-learning system in predicting the presence of disease, but with the local health-care system having the means to improve the health of its population.

Third, the real-world challenges discussed—such as the absence of universal electronic health record systems, slow internet connectivity, and operator-related and camera-related technical issues—are informative for future efforts to deploy a large scale deep-learning system for diabetic retinopathy screening, but currently have neither validated solutions nor established standards for the exchange of health information and artificial intelligence model outputs. Although efforts are underway for Digital Imaging and Communications in Medicine to standardise use of artificial intelligence

models in the clinical pathway, no communications standards for the exchange of retinal images and clinical data exist in ophthalmic care. Therefore, the authors' conclusion that artificial intelligence-guided semi-automation can be feasibly integrated into clinical workflow in an LMIC at scale will require refinement before such a claim is definitive.

Nonetheless, Ruamviboonsuk and colleagues[8] address an important step in the translation continuum[10] that aspires to bring advances in artificial intelligence to the bedside and ultimately amount to public health interventions with the potential to alter the course of ophthalmic morbidity in diabetes. The task of designing an optimal model of care to harness the potential of artificial intelligence, adjusted to the vagaries of the local socioeconomic climate in which it is deployed, is still in its infancy, but will surely continue to be the topic of important future work.

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