- **Automated diabetic retinopathy image assessment softwares: diagnostic accuracy and cost effectiveness compared to human graders**

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Abstract

Purpose:

With the increasing prevalence of diabetes, annual screening for diabetic retinopathy (DR) by expert human grading of retinal images is challenging. Automated DR image assessment systems (ARIAS) of retinal images may provide clinically and costeffective detection of retinopathy but to date the independent validity of ARIAS, and clinical applicability of different commercially available ARIAS to 'real life' screening has not been evaluated. The purpose of this study was determine if available ARIAS can safely be introduced into DR screening pathways and replace human graders.

Setting:

Consecutive patients with a diagnosis of diabetes mellitus, who attended their annual visit at their NHS Diabetes Eye Screening Programme in London.

Methods:

Retinal images from 20,258 consecutive patients attending routine annual diabetic eye check between 1st June 2012 and 4th November 2013. Retinal images were manually graded following a standard national protocol for DR screening and were processed by three ARIAS: iGradingM, Retmarker, and EyeArt. Discrepancies between manual grades and ARIAS were sent for arbitration to a reading center. Screening performance (sensitivity, false positive rate, likelihood ratios), and diagnostic accuracy (95% confidence intervals of screening performance measures) were determined. Secondary analysis explored the influence of patients' ethnicity, age, gender and camera on screening performance. Economic analysis estimated the cost per appropriate screening outcome.

Results:

Sensitivity point estimates (95% confidence interval) of the ARIAS were as follows: EyeArt 94.7% (94.295.2) for any retinopathy, 93.8% (92.994.6) for referable retinopathy (human graded as either ungradable, maculopathy, preproliferative or proliferative) 99.6% (97.099.9) for proliferative retinopathy; Retmarker 73.0% (72.074.0) for any retinopathy, 85.0% (83.686.2) for referable retinopathy 97.9% (94.999.1) for proliferative retinopathy. iGradingM classified all images as either having disease or being ungradeable. EyeArt and Retmarker were cost

saving compared to manual grading both as a replacement for initial human grading, or as a filter prior to primary human grading, although the latter approach was less costeffective

Conclusions:

Retmarker and EyeArt achieved acceptable sensitivity for referable retinopathy when compared with human graders and had sufficient specificity to make them costeffective alternatives to manual grading alone. ARIAS have the potential to reduce costs in developed world healthcare economies and to aid delivery of DR screening in developing or remote healthcare settings.