ORIGINAL ARTICLE

Credentialing & privileging an important factor for diagnostic accuracy of diabetic retinopathy screening in the health clinics of Penang

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ABSTRACT

Introduction: Early detection and management of diabetic retinopathy (DR) is crucial in preventing blindness. Screening is recommended at diagnosis and yearly for Type 2 diabetes patients. DR screening using non-mydriatic fundus cameras (NMFC) has been extended to Health Clinics since 1997, but competency and experience of the medical officers (MOs) remain an issue in Primary Care. This study aims to assess the accuracy of the eye examination using NMFC for DR screening done by MOs and identify the factors associated with the accuracy.

Materials and Methods: This is a cross-sectional study using secondary data obtained from the Penang State Health Department, which conducted clinical audits of fundus images from health clinics in 2019. The audit involved two consultant ophthalmologists to comment on the accuracy of the interpretation of retinal images and the quality of the images sampled from all health clinics with NFMC. Sampling was performed on the audited data set to include diagnosis by the MOs and diabetic retinopathy spectrum of disease. The subject of the study was the images with the corresponding reports. The outcome of this study was the accurate interpretation of the images, as commented by the ophthalmologists. The independent variables studied were the demographic of the MOs who interpreted the images, their training background and the quality of the images.

Results: The Universal sampling method was used, and the final 1129 images fulfilled the eligible criteria. The sensitivity, specificity, PPV and NPV were found to be 80.6%, 92.7%, 76.4% and 94.2%, respectively. Overall accuracy was 83.8%. After missing values were managed, 997 samples were analysed using logistic regression. The final model shows that significant factors associated with accuracy are foreign graduates MOs (Adjusted OR 1.98, 95% CI: 1.35-3.07), MOs with Credentialing & Privileging (Adjusted OR 2.32, 95% CI:1.32-2.88) and Good Image Quality (Adjusted OR 3.62,95% CI:2.37-5.71).

Conclusion: MO with C&P showed better accuracy than MO without C&P. This study suggests that MOH should emphasise the C&P when performing this procedure in health clinics. As image quality showed the highest association with accuracy, strengthening the C&P among the paramedics who perform the procedure using NMFC to get the retinal images is also necessary. This study also indicates that evaluating DR screening programs in health clinics is necessary nationwide.

KEYWORDS:
Non-Mydriatic Fundus Camera, Diabetic Retinopathy Screening, Health Clinics, Credentialing, Privileging, Training, Retinal Images, Fundus Images

INTRODUCTION

Diabetic Retinopathy (DR) is a condition with progressive retinal damage that occurs due to microvascular complications of diabetes mellitus. The global prevalence of DR among diabetic patients in 2021 was 22.27%,[1] and the National Diabetic Registry in 2020 shows that DR prevalence in Malaysia was 11.52%.[2] Furthermore, Diabetes Mellitus (DM) prevalence among adults in Malaysia has increased steadily over the past decade from 11.2% in 2011 and 13.4% in 2015 to 18.3% in 2019.[3] With the increasing trend in diabetic patients, DR prevalence and eye blindness from DR are projected to increase if no proper intervention is done.

Early detection of DR among DM patients with prompt management will significantly prevent blindness. Hence, it is crucial to have the screening at diagnosis and yearly for Type 2 DM patients.[4] Undiagnosed DR or late-stage diagnosis of DR is one of the problems identified. As reported in a study by Nor Farizah Ngah in 2020, 9% of the 3532 sampled patients had undiagnosed DR.[5] In another study by the University of Malaya in 2005, 28% of 217 diabetic patients sampled had undiagnosed PDR, a late-stage DR.[6] This is most likely due to the screening initiatives not being widely available then or not being detected by the treating physician for DM.

Malaysian Guidelines on DR Screening recommend using the Non-Mydriatic Fundus Camera (NMFC) as a screening tool for DR as it is the best modality of the screening tool for DR with 92% Sensitivity and 97% Specificity. This can ensure a high detection rate during screening and prevent delayed diagnosis.[7] However, NMFC was only made available at the ophthalmology clinic at the tertiary centre and operated by

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well-trained medical staff in the presence of an ophthalmologist.8 Given the increasing number of diabetic patients and the need for yearly screening for many patients using the best screening modality, DR screening using NMFC has been extended to Health Clinics since 1997.[8] The initiative is necessary as Health Clinics are the gatekeepers and the place where most DM patients in Malaysia are managed. The number of NMFCs made available in Health Clinics with diabetic management services continues to grow.

Two concerns raise doubts about whether extending NMFC to health clinics will achieve its intended purpose. One of them is the competency of the medical officers (MOs) in grading the fundus images. Fundus image grading was not part of the checklist of compulsory procedures doctors must perform during their horsemanship program in Malaysia.[9] Furthermore, MOs in health clinics do not have enough exposure and systematic training on par with those in the Ophthalmology Department in grading the fundus images.

Addressing this issue, MOH has developed a training module for medical staff to operate the machine and interpret the images since 2016 and incorporated it into the National Standard Program for Credentialing & Privileging (C&P).[8] However, the C&P for this procedure is not compulsory but highly recommended to MOs involved in grading the fundus images. Currently, no research has been conducted to assess whether using NMFC for DR screening in health clinics effectively detects DR in its early stages with an acceptable detection rate.

Realising this gap, the Penang State Health Department conducted an Audit in 2019 with more than 1600 images sampled and the reports by the MOs were commented on by the Ophthalmologists. These images are from about 800 patients. This is about 3% of the total screenings done in 2019.[10] However, the audit conducted was not specific to DR and the outcome was not measured using inferential statistics. Furthermore, factors associated with accuracy were not studied.[10] Therefore, this study examined the accuracy of interpretation of retinal images from NMFC for DR screening conducted by MOs and identified the factors associated with the accuracy, utilising the audit data from the Penang State Health Department.

MATERIALS AND METHODS

Study Design, Location, Period and Study Population

This is a cross-sectional study using secondary data. The secondary data refers to granular data from the audited image reports and ophthalmologist comments. Hence, the study population was Retinal Images, which were included in the clinical audits conducted in 2019 by the Penang State Health Department. The study period was from the 20th of March 2023 – 30th June 2023.

Process of Audit of Fundus Images in Penang (2019)

Penang State Health Department conducted audits of retinal images from health clinics in 2019 to evaluate the DR screening program in Health Clinics. A random sample of retinal images with reports was obtained from all health clinics with NMFC. Overall, 1632 images from 816 patients were included as samples, regardless of whether there were findings of the eye diseases (DR, Hypertensive Retinopathy, Glaucoma, etc.) or normal findings. Each image was given a code as a reference. The details of the reports, such as diagnosis, care plan and name of the medical officers who graded the images, were transferred to Form A. The images (in softcopy with codes) were sent together with Form A to two Ophthalmologist Consultants, each had half of the total reports to evaluate the diagnosis and plan of care. They commented based on the report (Form A) in Form B. Details in Form B are the Quality of images (satisfactory or poor), the diagnosis outcome (correct, partially correct and incorrect) and the appropriateness of the management (correct, partially correct and incorrect). Both Forms A & B were returned to the Penang State Health Department.

Sample Size and Sampling Method

Previous studies on the sensitivity and specificity of non-ophthalmologist graders of retinal images from Thailand and factors associated with Family Physicians' Performance on Competency assessment were cited for sample size calculations.[11-12] The calculation was done using Unmatched Case-Control (Fleiss with continuity correction Statistical Methods for Rates and Proportions) sampling calculation with 95% CI and 80% Power of Study. Ratio case over control 1.0. From the previous study, variable outcomes related to less percentage of unsafe competency are graded as the control group. The biggest sample size was selected, which was 816 samples of images with their respective audit records (Form A and Form B). The sampling frame is the list of Image Codes, and the sampling method was universal sampling methods in view of the strict eligible criteria of DR diagnosis.

Eligible Criteria from the Audit Data

Only DR eye diseases such as NPDR, PDR and Maculopathy and normal images reported by MOs were included in this study. The images that were not gradable by MOs or ophthalmologists were excluded.

Variables Studied

The subject of this study is the retinal images. The outcome variables studied were the diagnosis status (correct or incorrect) based on the audit data. As for Sensitivity, Specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV), the outcome was defined as True Positive, True Negative, False Positive and False Negative.

The independent variables studied are illustrated in Figure 1.

Data Management

The request was made to the Penang State Health Department to excess all reports of Form A and Form B. After the reports were screened and eligible images identified, data from the reports were transcribed into tables. MOs' identities were concealed, and the table was only made available for the desired variables related to the MOs, such as age, gender, years of experience, etc. This file is saved in a protected Word file with a password once the variables on the characteristics and training background of the medical officers are obtained. There is no possible bias that can be addressed in this secondary data collection and analysis process.

Table I: Sensitivity, Specificity, PPV & NPV of the NMFC Images Interpretation among MOs

Type of Analysis	Type of Scenario		
	Best Case (n=1129)	Worst Case (n=1129)	Absolute Case (n=1046)
True Positive	274	191	191
True Negative	750	750	750
False Positive	59	142	59
False Negative	46	46	46
Sensitivity	85.6%	80.6%	80.6%
Specificity	92.7%	84.1%	92.7%
PPV	82.3%	57.4%	76.4%
NPV	94.2%	94.2%	94.2%

Table II: Multiple Logistic Regression on the Factor Related to the Accuracy

Variables	B	S.E	Wald	df	Sig.	Exp(B)	95% C.I. for EXP (B)	
							Lower	Upper
Undergraduate Institution of the MO								
Local University (Reference)								
Foreign University	0.69	0.19	13.03	1	0.00	1.98	1.35	3.07
C&P Status of the MO								
No (Reference)								
Yes	0.84	0.18	21.63	1	0.00	2.32	1.23	2.88
Image Quality								
Poor (Reference)								
Satisfactory	1.29	0.21	36.58	1	0.00	3.62	2.37	5.71

Ethical Consideration

As explained above, this secondary data contains no names or personally identifiable variables. The database that contains the respective input of concern for variables is given study IDs, and the analysis is kept in a protected file. The excess will only be granted upon request for study validation purposes and improvement of service purposes.

This study was ethically cleared by the UiTM Ethical Committee and the Medical Research & Ethics Committee, Ministry of Health Malaysia (NMRR ID-24-00966-VFS).

Statistical Analysis Plan

IBM SPSS version 26 was used for statistical analyses. All the data are categorised and expressed as frequencies and percentages.

The operational definition for the accuracy analyses are as follows:

a) True positive (TP) = number of retinal images with positive findings correctly diagnosed by the MOs
b) True Negative (TN) = number of normal images correctly reported by the MOs
c) False Positive (FP) = number of retinal images with normal findings but incorrectly diagnosed by MOs.
d) False Negative (FN) = number of retinal images with positive findings but incorrectly graded as normal by MOs.

These definitions were extended to include the calculations of Sensitivity, Specificity, PPV and NPV:[13]

Sensitivity = TP/ (TP + FN)
Specificity= TN/ (TN + FP)
PPV= TP/ (TP + FP)
NPV= TN/ (TN + FN)
Overall Accuracy: (TP + TN)/ (TP + TN + FP + FN)

To elucidate the factors associated with image interpretation accuracy, simple logistic regression (SLR) was conducted. Subsequently, Multiple Logistic Regression (MLR) analysis was performed, incorporating adjustments for all variables. Statistical significance was determined at a threshold of $p<0.05$.

RESULTS

Sample Outcomes and Missing Data Management

From the 1632 images, 1129 samples were included in the descriptive analysis for Sensitivity, Specificity, PPV and NPV. The details of the process are shown in Figure 2 and the findings were presented in Table I. The secondary data for the dependent variable has three categories (correct, partially correct and incorrect), so the findings were classified according to three different scenarios. The Best Case Scenarios defined partially correct as correct, the Worst Case Scenarios defined partially correct as incorrect and in the Absolute Case Scenarios, partially correct was omitted.

Missing values were found in the variable of MO's age during the procedure (19.6%), years in service (2%) and years of experience in Primary Care during the procedure (5%). The missing values are also found in the variables for C&P Status (3%), Post Graduate Training Status (8%), Undergraduate Institutions Status (2%) and Image Quality (only one image). These resulted in 225 images (19.9%) with at least one missing value. MCAR (Missing Completely At Random) test was then performed, which resulted in the chi-square value of 0.525 with 1 degree of freedom (df), and the associated p-value was 0.469. This suggests that the missing data are missing completely at random. The imputation method was used to fill in missing MO age values based on common ages (mode/mean) corresponding to Years in Service. Listwise deletion was applied to the other variables' missing values,

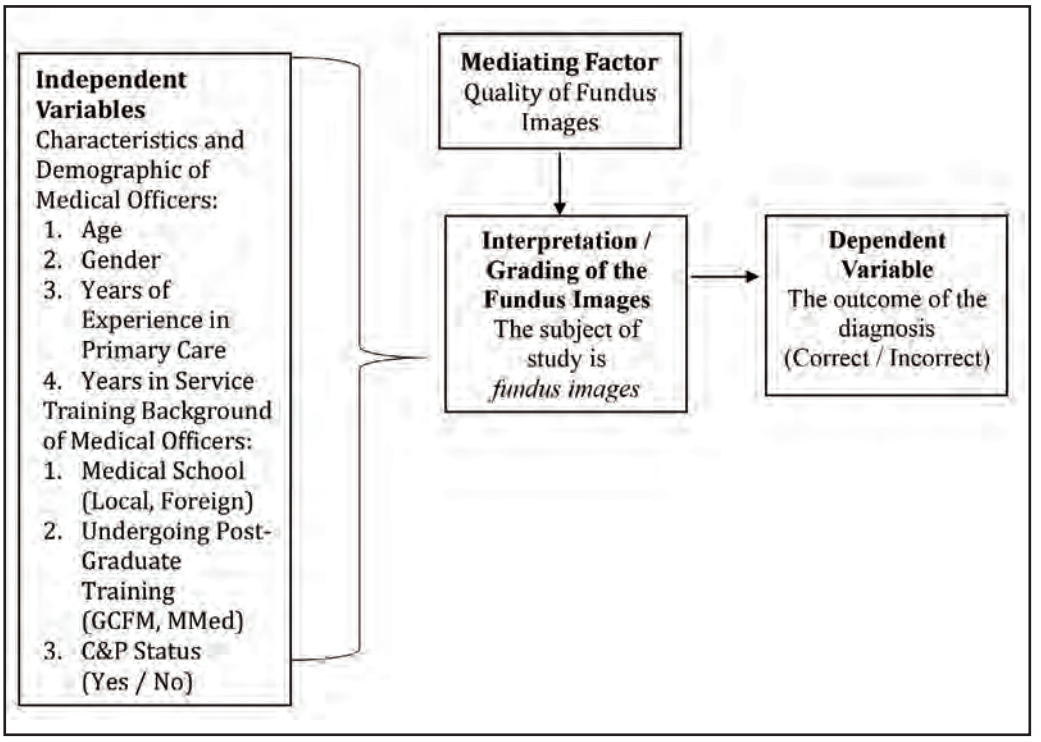

Fig. 1: Independent and Dependent Variables Studied

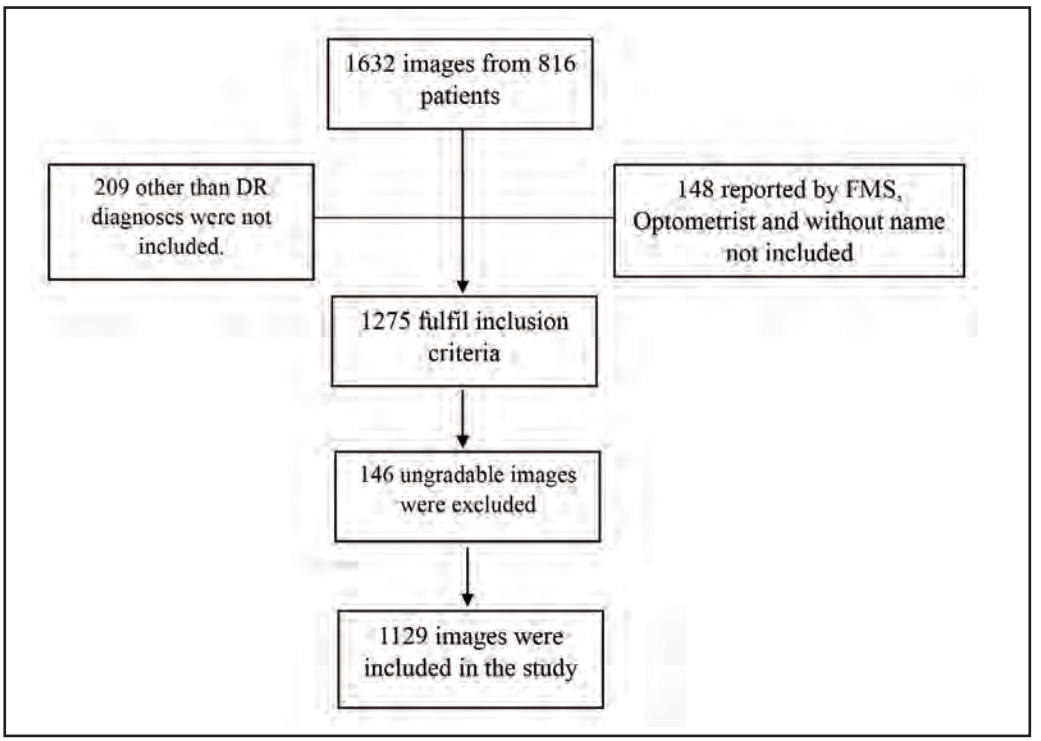

Fig. 2: The outcome of the data sampling process

which led to the total final data included in the analytical analysis, which was 997 image reports. In this analysis, 'partially correct' findings were regrouped as 'incorrect' to maintain dichotomous outcomes.

Logistic Regression

Overall, the accuracy of the examination was 83.8%. All the variables were then entered into MLR using backward and forward LR methods for the adjustments. This process resulted in only 3 significant variables, which are significant and fit well with the data (Hosmer-Lemeshow Test p-value; 0.815).

The statistically significant variables were Undergraduate Institution Status, C&P Status and Image Quality. Multicolinearity was checked, and all VIF values ranged between 1 and 2, indicating no significant collinearity between the variables. No interaction was found between these three variables. The outcome of the MLR is shown in Table II. High adjusted OR for correct diagnosis was found in images which were graded satisfactory by the Ophthalmologists (Adjusted OR 3.62, 95% CI:2.37-5.71) followed by C&P status (Adjusted OR 2.32, 95% CI: 1.23-2.88). The above result also showed that MOs who graduated from foreign universities have better accuracy of DR using NMFC (Adjusted OR 1.98, 95%CI:1.35-3.07). The logistic regression model yielded a Cox & Snell R-Square value of 0.65, indicating that approximately 65% of the variation in the outcome of the accuracy of DR screening using NMFC is explained by the Undergraduate Institution and C&P status of the MOs as well as the Image Quality.

DISCUSSION

This study shows that in absolute case scenarios, the sensitivity and specificity of DR screening using NMFC by MOs in Health Clinics of Penang were 80.6% and 92.7%, respectively. Multiple studies have been conducted to evaluate the accuracy of DR using NMFC with reference to Ophthalmologists.

Somanguan conducted a diagnostic study on non-expert retinal image graders in Thailand health clinics in July 2021 and found that the sensitivity for DR was only 67%.[14] Another study conducted in 2021 among the non-expert medical staff at the Peripheral Health Facilities of Bangladesh found that the sensitivity was 87% and the specificity was 93%.[15] A Pilot Study was conducted in 2018 to look for concordance of Optometrist findings with Ophthalmologists, and the result shows a high concordance of 87.0% with Ophthalmologists.[16] Hence, this study demonstrates results similar to non-expert retinal image grades in other studies.

Even though SLR showed no significant association between C&P status and accuracy, after MLR was performed to adjust with all variables, C&P was shown to have a significant association with accuracy. This shows the importance of C&P in increasing retinal image interpretation skills among MOs. Increasing the number of MOs with C&P or making it compulsory can improve the overall accuracy of this screening procedure.

So far, no study has been done to associate any factors towards the outcome of retinal image grading/interpretation accuracy among doctors nationally or internationally. However, multiple studies have been conducted to associate factors with certain competencies and practices among doctors and other medical professions. A study of 683 physicians referred to the Center for Personalized Education for Physicians in Denver between 2000 and 2010 found that board certification and matched training were associated with safe assessment outcomes.[12]

A study in 2014 regarding factors influencing diagnostic accuracy and management in acute surgical patients in a hospital in the UK found that the consultant was most likely to record a correct diagnosis (75%), followed by SHO (61.3%) and SROC (61.1%).[17] Another study in Shanghai in 2019 found that educational background and job training were among the factors affecting family doctor competency.[18] In all of these studies, job or specific training has consistently been associated with competency, which is similar to this study regarding C&P.

Furthermore, according to this study, foreign graduate Medical Officers (MOs) have higher accuracy in interpreting retinal images. This is likely due to the curriculum provided by foreign institutions, which emphasises this skill more. The Ministry of Health (MOH) should inform local universities about this matter so that they can improve their curriculum and place more emphasis on retinal image interpretation.

Image quality plays an utmost important role in affecting the judgment of the MOs in the interpretation. Good image quality has been shown to have an adjusted OR of a correct diagnosis of 3.62 (95% CI:2.37-5.71), the highest OR in this study. A study was conducted on the assessment of image quality on colour fundus retinal images using automatic retinal image analysis, and the result showed that even software has a significant difference in sensitivity and specificity with regard to image quality.[19] Retinal images in health clinics are taken by the paramedics while the medical officer interprets them.[8] Hence, it is important for the MOH to train the paramedics concurrently and make the C&P on operating the NMFC compulsory for them to perform this procedure.[8]

The latest technological advancement has brought artificial intelligence (AI) to diagnose fundus images. Datuk Dr Nor Farizah Ngah presented MOH's latest initiative, DR.MATA, at a National Institute of Health session on 25th May 2023. She stated that DR.MATA is an AI developed by MOH that is to be implemented in health clinics to interpret fundus images. A study of more than 14000 images showed the sensitivity of this AI is 87.17%, the specificity is 97.17%, and the accuracy is 93.3%.[20] These values are slightly superior to those of the findings from this study, but the difference is minimal. Utilising AI is a timely initiative by MOH. However, if there are technical or financial problems maintaining the system, MOH should consider training and providing more MOs with C&P. This alternative can be achieved with a relatively smaller budget and have a more sustainable impact. A cost-effective analysis can be done to compare the efficacy of both initiatives.

This study has some limitations, mainly due to the use of secondary data. Even though the missing values are not more than 20% of the overall data, conducting the study primarily will improve the availability of the data set to be analysed. This study may serve as baseline findings that can be generalised to other states in Malaysia as there is no significant geographical impact on the accuracy of the eye examination using NMFC.

CONCLUSION

NMFC is an important modality of the DR screening programme in Malaysia. It has been extended to Primary Care to increase the screening of DR among DM patients,

which is growing in numbers as timely diagnosis and prompt treatment can prevent blindness from DR. This diagnostic accuracy study suggested that the MOs, which play the most crucial role in interpreting the images have adequate interpretation capabilities given that they are provided with C&P. Foreign graduates and good image quality shows significant association towards correct interpretation apart from C&P status. The MOH should improve C&P procedures for both MOs and paramedics and ensure more of them receive training. It is recommended that the MOH conduct multicentered studies throughout Malaysia to evaluate the effectiveness of the screening program, as millions of ringgit have been invested in this program, and the prognosis of patients with DR greatly depends on it.

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DECLARATION OF INTEREST

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