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HAND HELD FUNDUS CAMERA

HEALTH TECHNOLOGY ASSESSMENT SECTION (MaHTAS) MEDICAL DEVELOPMENT DIVISION
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DISCLAIMER

Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It has been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

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DISCLOSURE

The author of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.

EXECUTIVE SUMMARY

Background

Evolution of fundus camera starts from the invention of ophtalmoscope in 1851 by Herman Von Hemholtz which provide visualization of the posterior segment of the eye by ophthalmologist. The first reliable fundus camera was then introduced by Carl Zeiss and J.W. Nordensen in 1926 and this allowed documentation of ocular fundus structure. Troughout the years, camera systems have evolved to boast sharper images, nonmydratic wide field options, pupil tracking and most recently is portability.

Traditional fundus camera offers good quality images but are bulky, office based, technician dependent and costly. The need for modern table top fundus camera device has emerged from specific limitations that accompany the use of traditional table top fundus camera. However, most of modern table top fundus cameras have add-on features that contribute to additional size and weight of camera. It is essentially an office based and very costly and the application in primary healthcare may be limited due to constraint.

A prototype hand held fundus camera was designed by interfacing an optical module with Panasonic Lumix G2 consumer camera providing a 50º retinal field of view. The images produced by the prototype camera is claimed to be comparable to standard fundus camera.

This technology review was conducted based on request from Pahang State Health Director, to assess the suitability or feasibility of using hand held fundus camera as an alternative screening tool to screen for diabetic retinopathy in clinics across Pahang State.

Objective/aim

The objective of this technology review was to assess effectiveness, safety and cost- effectiveness of hand held fundus camera for detecting diabetic retinopathy, hypertensive retinopathy or other retinal disorders such as age related macular degeneration, and glaucoma.

Results and conclusions

A total of 186 titles were identified through the Ovid interface and PubMed. Only seven studies were included in this review on the efficacy/effectiveness of hand held fundus camera.The evidence retrieved for screening of diabetic retinopathy using hand held fundus camera was inconclusive, whereby one study reported low sensitivity and specificity 6.9% [95% Confidence Interval (CI): 2.3, 11.5] and 50% (95% CI: 0,100) respectively in detecting minimal non proliferative diabetic retinopathy while another study reported high sensitivity and specificity in detecting any grade retinopathy (sensitivity and specificity of 93% and 98% respectively by ophthalmologist while medical officer reported 92% and 95%

sensitivity and specificity respectively). There was limited fair level of retrievable evidence to suggest that hand held fundus camera has the potential to be used for detecting of retinopathy of prematurity (ROP), and glaucoma. There was no evidence retrieved on the safety and cost-effectiveness of hand held fundus camera in clinical setting.

Methods

Electronic databases were searched through the Ovid interface: MEDLINE(R) In-Process and Other Non-Indexed Citations and Ovid MEDLINE (R) 1946 to present, EBM Reviews – Cochrane Central Registered of Controlled Trials – November 2015, EBM Reviews – Database of Abstracts of Review of Effects – 2nd Quarter 2015, EBM Reviews – Cochrane Database of Systematic Reviews – 2005 to November 2015, EBM Reviews – Health Technology Assessment – 4th Quarter 2015, EBM Reviews - NHS Economic Evaluation Database – 2nd Quarter 2015. Searched were also run in PubMed. Google and Google Scholar were used to search for additional web-based materials and information.

A critical appraisal of the retrieved papers was performed and the evidence level was graded according to the NHS Centre for Reviews and Dissemination (CRD) University of York.

HAND HELD FUNDUS CAMERA

1. BACKGROUND

Fundus photography involves capturing a photograph of the back of the eye or fundus using specialised fundus camera. The main structures that can be visualised on a fundus photo are peripheral retina, optic disc and macula. They are also used to document abnormalities of disease process affecting the eye and to follow up the progress of the eye condition such as diabetes, age macular degeneration, glaucoma, neoplasm of the choroid, cranial nerves, retinal/eyeball, and etc.[1]

Evolution of fundus camera starts from the invention of ophtalmoscope in 1851 by Herman Von Hemholtz which provide visualization of the posterior segment of the eye by ophthalmologist. The first reliable fundus camera was then introduced by Carl Zeiss and J.W. Nordensen in 1926 and this allowed documentation of ocular fundus structure. The camera provided 20º field of view but then was improved to 30º field of view as a standard of ocular fundus photography. Throughout the years, camera systems have evolved to boast sharper images, nonmydratic wide field options, pupil tracking and most recently is portability.[2]

Traditional fundus camera offers good quality images but are bulky, office based, technician dependent and costly. The need for modern table top fundus camera device has emerged from specific limitations that accompany the use of traditional table top fundus camera. However, most of modern table top fundus cameras have add-on features that contribute to additional size and weight of camera. It is essentially an office based and very costly and the application in primary healthcare may be limited due to constraint.[2]

A prototype hand held fundus camera was designed by interfacing an optical module with Panasonic Lumix G2 consumer camera providing a 50º retinal field of view. The images produced by the prototype camera is claimed to be comparable to standard fundus camera.[3]

This technology review was conducted based on request from Pahang State Health Director, to assess the suitability or feasibility of using hand held fundus camera as an alternative screening tool to screen for diabetic retinopathy in clinics across Pahang State.

2. OBJECTIVE/AIM

The objective of this technology review was to assess the effectiveness, safety and cost- effectiveness of hand held fundus camera for detecting diabetic retinopathy, hypertensive retinopathy or other retinal disorders such as age related macular degeneration, and glaucoma.

3. TECHNICAL FEATURES

Hand held fundus camera is claimed to be very light, portable, easy to use, did not require space and not technically dependent and much cheaper.[4] The optical design of hand held fundus camera is based on the principle of the monocular indirect ophthalmoscopy which provides upright, magnified view of the fundus. There are a few brands of hand held fundus camera available in the market such as Zeiss, Canon, Kowa, Optomed and etc. with various specifications such as: [2]

- design principal (reflective imaging using white light, reflective imaging only, conventional optics or slit lamp based)
- use mydratic or non mydratic
- degree field of view (ranging from 25º to 40º) of 360 º
- focusing range (- 20D to + 20D)
- fixation target and image sensor display
- Image sensor or display ranging from 2 to 5 megapixel camera with LCD display
- additional features such as color imaging, general examinations and anterior eye module and can be connected to external devices via either USB of Wifi connectivity
- Image storage varies depending on brand such as image memory 30 image files in flash memory function for Nidek NM100 and 4GB SD memory card for Volk Pictor camera[5,6]

Figure 1: Example of hand held fundus camera available in market[3]

4. METHODS

4.1. Searching

Searching Electronic databases searched through the Ovid interface:

- MEDLINE(R) In-Process and Other Non-Indexed Citations and Ovid MEDLINE (R) 1946 to present
- EBM Reviews – Cochrane Central Registered of Controlled Trials – November 2015
- EBM Reviews – Database of Abstracts of Review of Effects – 2nd Quarter 2015
- EBM Reviews – Cochrane Database of Systematic Reviews – 2005 to November 2015
- EBM Reviews – Health Technology Assessment – 4th Quarter 2015
- EBM Reviews - NHS Economic Evaluation Database – 2nd Quarter 2015

Other databases:
- PubMed
- Horizon Scanning website (National Horizon Scanning Centre, Australia and New Zealand Horizon Scanning Network, National Horizon Scanning Birmingham)
- Other websites: U.S. Food and Drug Administration (US FDA)

General databases such as Google and Google Scholar were used to search for additional web-based materials and information. Additional articles retrieved from reviewing the references of retrieved articles. The search was limited to articles on human. There was no language limitation in the search. Appendix 1 showed the detailed search strategies.

4.2. Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full-text articles for final article selection. The inclusion and exclusion criteria were:

Inclusion criteria

Population	Patient with diabetes , hypertension, retinal disease, glaucoma
Interventions	Hand held fundus camera
Comparators	Table top fundus camera, no comparator
Outcomes	Sensitivity and specificity, accuracy, adverse events, agreement (k), cost-effectiveness
Study design	HTA report, systematic review (SR), randomised controlled trial (RCTs), Diagnostic accuracy study, cross-sectional, cohort, case control, case series
	English full text article

Exclusion criteria

Study design	Case report, anecdotal claim, animal studies
	Non-English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) checklist and evidence graded according to the NHS Centre for Reviews and Dissemination (CRD) University of York, Report Number 4 (2nd Edition) (Appendix 2). Data were extracted from included studies using a pre-designed data extraction form (evidence table as shown in Appendix 3).

5. RESULTS AND DISCUSSION

The search strategies yielded 186 articles on the hand held fundus camera. Seven studies were included in this review which consisted of five diagnostic accuracy studies and two cross sectional studies. However, there was no retrievable evidence on the safety and cost-effectiveness of this technology.

5.1 EFFICACY/ EFFECTIVENESS

From the seven studies retrieved on efficacy/effectiveness of the hand held fundus camera, four studies were on diabetic retinopathy, two studies were on Retinopathy of Prematurity (ROP) and one study on glaucoma.

Diabetic retinopathy

Saari JM et al. conducted a diagnostic accuracy study in 2004 to assess the performance of three digital fundus camera: Topcon TRC 50IA [(table top) – digital fundus imaging], Canon CR6-45NM [(table top) – digital polaroid fundus camera] and Meditell [(Hand held) – digital colour video camera] for diabetic retinopathy screening. There were 427 images of 42 diabetic patients and 28 healthy medical student as control subjects which were graded by three readers. Sensitivity of digital 50°red free imaging, two field 50°colour imaging and two field 45°colour imaging (obtained from Topcon TRC 50IA and Canon CR6-45NM) was 97.7%, 94.0% and 98.9% respectively. The overall specificity of these imaging modilities was 98.9% - 100% and under gradable images represented 1.2-1.6%. However, the hand held digital colour video camera (Meditell) showed a sensitivity of 6.9% in all graders and under gradable images represented as 92.3%. The sensitivity and specificity of Meditell in comparison with reference standard for detection minimal Non Proliferative Diabetic Retinopathy (MNPDR) was 6.9% [95% Confidence Interval (CI): 2.3, 11.5] and 50% (95% CI: 0,100) respectively.[7, level 1]

A cross sectional study was conducted by Yogesan K et al. to evaluate digital images of the retina from a handheld fundus camera for suitability in telemedicine screening of diabetic retinopathy. A hand held fundus camera (Nidek-NM100) and a standard fundus camera (Zeiss) were used to photograph 49 eyes from 25 consecutive patients attended the diabetic

clinic. The Nidek images were digitized, compressed and stored in a Fujix DF-10M digitizer supplied with the camera. The digital images and photographs were presented separately in a random order to three ophthalmologists. The quality of images were ranked as good, acceptable and unacceptable for diabetic retinopathy diagnosis. The images were also evaluated for the presence of microaneurysms, blot haemorrhage, exudates, fibrous tissue, previous photocoagulation and new vessel formation. Twenty four percent of digital images and corresponding photographs were assessed as being of good quality, 53% of digital images were of acceptable quality and 16% of the digital images were graded as unacceptable quality. For each ophthalmologists, there was poor agreement between the assessment of the photographs and digital images (*k* <0.30). Agreement between the ophthalmologists for assessments of the photographs was high (average correlation coefficient=0.8) but low for grading of the digital images (average correlation coefficient=0.36)[8]

A cross sectional study by Yogesan K et al. conducted on eleven patients (10 diabetics and one non diabetic) in prison using the hand held fundus camera (Nidek NM-100 and Nidek NM-1000D).The objectives of the study were to provide specialist ophthalmic care to prisoners without transporting them to external hospital and to train prison medical officers and nurses to use equipment to screen prisoners for disease of the anterior segment or retina. They reported that the retinal images obtained from both camera were able to image posterior pole, including the optic nerve head. The quality of retinal images obtained with or without dilation was considered either moderate or poor for diabetic retinopathy diagnosis but was adequate to access optic disc cupping. It was not possible to identify any indication of diabetic retinopathy from the retinal images.[9]

Ting et al. conducted a diagnostic accuracy study to validate the economical portable multipurpose ophthalmic imaging device (Eyescan) for diabetic retinopathy screening in the community. One hundred and thirty six diabetic patients (272 eyes) underwent three field optic disc, macular and temporal view mydratic retinal still photography captured by Eyescan (portable device) and table top fundus camera, [FF450 plus (Carl Zeiss)] and were subsequently examined by a senior consultant ophthalmologist using slit lamp biomicroscopy as reference standard. All retinal images were interpreted by a consultant ophthalmologist and a medical officer. For detection of any grade of diabetic retinopathy, Eyescan had a sensitivity and specificity of 93% and 98% respectively by ophthalmologist while medical officer reported 92% and 95% sensitivity and specificity respectively. In contrast, FF450 plus images had a sensitivity and specificity of 95% and 99% respectively (detection by ophthalmologist) whereas 92% and 96% respectively (detection by medical officer). The overall kappa statistic of diabetic retinopathy grading

for Eyescan and FF450 plus were 0.93 and 0.95 for ophthalmologist and 0.88 and 0.90 for medical officer respectively as compared to reference standard.[10, level 1]

Retinopathy of Prematurity (ROP)

A diagnostic accuracy study was conducted by Prakalapakorn SG, Wallace DK and Freedman S, to assess the feasibility of using Pictor digital hand held fundus camera (field of view 40°) to obtain high quality retinal images and the accuracy of grading the images by two ROP experts for clinically significant posterior pole vascular changes (pre-plus or plus disease) compared to indirect ophthalmoscopy in 96 eyes of 48 premature infants. They reported that mean field of view for disk diameter (DD) was 5.5 x 6.1 for retinal images obtained using Pictor digital fundus camera. Quality of the images when compared to the cropped images from the International Classification of ROP (ICROP) Revisited publication was found to be fair or good in 96% in grader 1 and 97% in grader 2. Grader 1 judged 80% of images as having at least 1 DD length of major vessel in three or four quadrants while 86% in grader 2 judgement. The sensitivity and specificity of grading pre-plus or plus disease on Pictor digital fundus camera images was 100% and 79% respectively for grader 1 and 83% and 85% respectively for grader 2 as compared to reference standard of indirect ophthalmoscopy.[11, level 2]

Shah et al. compared photographic screening for ROP using Retcam 120 (hand held fundus camera) with Binocular indirect ophthalmoscope (BIO). A total of 87 Retcam examinations were performed on 27 premature babies. Retinopathy of prematurity was detected in 63 of 87 examinations by BIO and 56 of Retcam examinations. Nine Retcam examinations were false negative and two were false positive. Sensitivity of Retcam was 85.11% and specificity was 91.66%. The positive and negative predictive values were 96.43% and 70.97% respectively.[12, level 2]

Glaucoma

A diagnostic accuracy study was conducted by Yogesan K et al. on 43 subjects (average age 60 years old) who were screened for glaucoma. Images of both eyes were obtained using Digital Indirect Ophthalmoscope (DIO), hand held fundus camera (Nidek NM-100), and stereo fundus camera (Nidek 3D-x) used as gold standard. The correlation coefficient between DIO images and hand held fundus camera compared to gold standard was 0.80 and 0.76 respectively. Vertical cup-disc ratio (VCDR) for hand held fundus camera gives 84% specificity and 100% sensitivity while DIO gives 87% specificity and 100% sensitivity. Overall, 8% of hand held fundus camera images and 30% of DIO images categorized as poor in quality. However, further modifications were needed to make the

instrument more user friendly and to enable it to be used with undilated pupils.[13, level 3]

5.2 SAFETY

There was no retrievable evidence on adverse events of hand held fundus camera. However, the hand held fundus camera had received 510k from United States Food and Drug Administration (USFDA).

5.3 COST-EFFECTIVENESS

There was no retrievable evidence on the cost-effectiveness of hand held fundus camera. However, the price of the hand held fundus camera is estimated from [redacted] while estimated price for table top fundus camera is [redacted]

5.4 LIMITATION

Our review has several limitations. The selection of the studies and appraisal was done by one reviewer. Although there was no restriction in language during the search, only English full text articles were included in the report.

6. CONCLUSION

The evidence retrieved for screening of diabetic retinopathy using hand held fundus camera was inconclusive, whereby one study reported low sensitivity and specificity in detecting minimal non proliferative diabetic retinopathy while another study reported high sensitivity and specificity in detecting any grade retinopathy. There was limited fair level of retrievable evidence to suggest that hand held fundus camera has the potential to be used for detecting of ROP, and glaucoma. There was no evidence retrieved on the safety and cost-effectiveness of hand held fundus camera in clinical setting.

8. REFERENCES

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2. Panwar N, Huang P, Lee J at al. Fundus Photography in the 21st Century- A Review of recent Technological Advances and Their Implications for Worldwide Healthcare. Telemed and e-Health. 2016; 22 (3): 1-11.

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9. APPENDIX

9.1. Appendix 1: LITERATURE SEARCH STRATEGY

Ovid MEDLINE® In-process & other Non-Indexed citations and OvidMEDLINE® 1946 to present

1 DIABETES MELLITUS/ (97857)

2 DIABETES MELLITUS.tw. (140822)

3 DIABETES MELLITUS, TYPE 1/ (66080)

4 iddm.tw. (6838)

5 ((insulin dependent or insulin-dependent or type I or type 1) adj1 diabetes mellitus 1).tw. (16)

6 DIABETES MELLITUS, TYPE 2/ (98723)

7 niddm.tw. (6921)

8 ((noninsulin-dependent or noninsulin dependent or type 2 or type ii) adj1 diabetes mellitus).tw. (30660)

9 HYPERTENSION/ (204621)

10 (blood pressure* adj1 high).tw. (12095)

11 hypertension.tw. (305165)

12 OCULAR HYPERTENSION/ (5838)

13 (glaucoma* adj1 suspect*).tw. (1040)

14 (hypertension* adj1 ocular).tw. (4277)

15 INTRACRANIAL HYPERTENSION/ (3567)

16 ((hypertension or (pressure increase or elevated)) adj1 intracranial).tw. (6955)

17 RETINAL DISEASES/ (17957)

18 (retinal adj1 disease*).tw. (3712)

19 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 (681988)

20 hand held fundus camera.tw. (10)

21 table top fundus camera.tw. (0)

22 fundus camera.tw. (726)

23 20 or 21 or 22 (726)

24 19 and 23 (122)

OTHER DATABASES	
EBM Reviews - Cochrane Central Register of Controlled Trials	Same MeSH, keywords used as per MEDLINE search
EBM Reviews - Database of Abstracts of Review of Effects	
EBM Reviews - Cochrane database of systematic reviews	
EBM Reviews - Health Technology Assessment	
PubMed	(((diabetes mellitus) OR hypertension) OR retinal disease) AND (((hand held fundus camera) OR fundus camera))
NHS economic evaluation database	

9.2. Appendix 2: HIERARCHY OF EVIDENCE FOR TEST ACCURACY STUDIES

Level	Description	
1.	A blind comparison with reference standard among an appropriate sample of consecutive patients	
2.	Any one of the following	Narrow population spectrum
3.	Any two of the following	Differential use of reference standard
4.	Any three or more of the following	Reference standard not blind Case control study
5.	Expert opinion with no explicit critical appraisal, based on physiology, bench research or first principles	

SOURCE: NHS Centre for Reviews and Dissemination (CRD) University of York, Report Number 4 (2nd Edition)

9.3. Appendix 3

Evidence Table : Effectiveness

Question : What is the effectiveness of hand held fundus camera

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
1) Saari JM et al, Sensitivity and specificity of digital retinal images in grading diabetic retinopathy. Acta Opthtalmol Scand. 2004; 82: 126-130	**Study design:** Diagnostic accuracy study **Objective:** To compare sensitivity and specificity of three novel digital fundus cameras for diabetic retinopathy screening. 1)Topcon TRC 50IA (table top) – digital fundus imaging 2) Canon CR6-45NM (table top) – digital polaroid fundus camera 3) Meditell (Hand held) – digital colour video camera **Methods:** All subjects underwent ophthalmoscopic examination including assessment of corrected visual acuity (VA), slit lamp biomicroscopy, measurement of intraocular pressure (IOP) using Goldmann applanation tonometer and examination of the ocular fundus through dilated pupils by experienced ophthalmologist. **1)Digital Imaging**: All digital retinal imaging, the pupils were dilated with 0.5% tropicamide and 10% phenylephrine eye drop. Topcon TRC 50 IA used to	1	Total 70 subjects 37 men,33women aged between 22 and 83 years (mean 41.8 ± 19.1 years, median age 31years) 42 subject (28M, 14W; age range 23-83 years, mean 53.2 ±16.8 years had diabetes (79 examined eyes) 17 of them (40.5%) had type 1 DM and 25 (59.5%) had type ii DM Diabetes had been diagnosed in the mean at the age of 33.3±21.4 years (median 40years, range 3-76 years) and the mean duration of the disease was 19.8 ±12.2 years (median 18.5 years, range 1-44 years). 40 patients had Diabetic	i)Topcon TRC 50IA ii)Canon CR6-45NM iii)Hand held digital colour video camera (Meditell)	-	-	**Result:** Digital red-free imaging showed the best sensitivity (97.7%; 95% CI 95.8–99.7) and digital colour imaging the second best sensitivity (94%, 95% CI 90.8–97.2 for the Topcon TRC 50 IA; 88.9%, 95% CI 82.0–95.8 for the Canon CR6–45NM) when compared with the reference standard. There were no statistically significant differences in the specificity between digital red-free (98.9%, 95% CI 96.7–100) and colour imaging (99.0%, 95% CI 96.9– 100 for the Topcon TRC 50 IA; 100% for the Canon CR6–45NM) for detection of at least mild NPDR when compared with the reference standard. Digital red-free imaging showed 98.1% and digital colour imaging 95.5% (Topcon TRC 50 IA) and 89.3% (Canon CR6–45NM) exact agreement for detection of at least mild NPDR when compared with the reference standard. Digital red-free imaging showed only 0.3% and digital colour imaging 2.6% (Topcon TRC 50 IA) and 9.5% (Canon CR6–45NM) of undercalls for detection of at least mild NPDR when compared with the reference standard. In all imaging modalities and in all graders the overcalls varied between 0% and 1.0%. Only 1.3% of digital red-free images and 1.2–1.6% of digital colour images (Topcon and Canon) were ungradeable . The hand-held digital colour	

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
	take two 50 digital color images (1 red free, black and white image using the green filter supplied by manufacturer Canon CR6-45NM used to take two 45°digital colour images per eye. One field covered temporal area, including macula and disc. Second field covered nasal area including disc. Meditell used for digital imaging of the central parts of the ocular fundus. Two single still images were taken using a white-light flash for illumination. All images were captured by a professional photoghapher. Digital retinal imaging was carried out on 108 eyes (total images=427). Of 108 eyes, 106eyes - 50°retinal colour imaging 106 eyes – red free imaging (Topcon) 104 – examined under both modalities Digital 45°retinal colour imaging (Canon) was carried out on 29 eyes(54 images) Hand held digital colour video camera (Meditell) was used for imaging of 44 eyes(83 images)		retinopathy. 31 patients had been treated with photocoagulation (56 examined eyes). 28 patients were treated with insulin, 12 with oral medication and 2 with both. 28 subjects were healthy medical students used as control (29 examined eyes) 10M ,18W; aged between 22 and 31 years (mean 24.7±1.7 years) All subjects underwent ophthalmoscopic examination including assessment of corrected visual acuity (VA), slit lamp biomicroscopy, measurement of intraocular				videocamera showed only 6.9% (95% CI 2.3–11.5) sensitivity and 50% (95% CI 0–100) specificity for detection of at least mild NPDR when compared with the reference standard. There was good intergrader agreement between graders A, B and C for all four imaging modalities Sensitivity and specificity of mydriatic digital retinal imaging in comparison with the reference standard for detection of different diagnostic groups of DR. Data are percentages (95% CI). 1) Topcon colour **Sensitivity** Minimal NPDR 96.3 (93.8– 98.8) Mild NPDR 94.0 (90.8–97.2) Moderate NPDR 88.3 (83.3–93.3) Severe NPDR 79.2 (70.1–88.3) PDR 59.1 (44.4–73.8) **Specificity** Minimal NPDR 99.0 (96.9–100) Mild NPDR 99.0 (96.9–100) Moderate 96.0 (92.9–99.1) Severe NPDR 93.2 (90.0–96.4) PDR 97.0 (95.0–99.1) 2) Canon **Sensitivity** Minimal NPDR 92.6 (86.9–98.3) Mild NPDR 88.9 (82.0–95.8) Moderate NPDR 86.5 (77.1–95.9) Severe NPDR 20.0 (0–42.2) PDR 0 **Specificity** Minimal NPDR 100 Mild NPDR 100 Moderate NPDR 90.6 (80.4–100)	

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
	2) Experiment Protocol and grading of diabetic retinopathy: A random code was assigned to each eye camera combination. The digital images and the corresponding codes were sent in electronic form for assessment to three graders (A,B and C) They were masked to all clinical and personal data of the patients and to the grading results of the other screener. The images were graded for DR by three readers in a randomized and masked manner using modified Early treatment Diabetic retinopathy study classification. The reference standard was based on mydratic ophthalmoscopy carried out by ophthalmologist and the use of digital retinal colour and red-free images.						Severe NPDR 100 PDR 100 3) MediTell **Sensitivity** Minimal NPDR 6.9 (2.3–11.5) Mild NPDR 6.9 (2.3–11.5) Moderate NPDR 3.5 (0.1–6.8) Severe NPDR 0.9 (0–2.7) PDR 0 **Specificity** Minimal NPDR 50 (0–100) Mild NPDR 50 (0–100) Moderate NPDR 50 (0–100) Severe NPDR 54.5 (23.7–85.4) PDR 53.3 (27.2–79.5) 4 Topcon red-free **Sensitivity** Minimal NPDR 98.2 (96.4–100) Mild NPDR 97.7 (95.8–99.7) Moderate NPDR 93.9 (90.3–97.6) Severe NPDR 86.1 (78.4–93.8) PDR 71.1 (57.7–84.5) **Specificity** Minimal NPDR 98.9 (96.7–100) Mild NPDR 98.9 (96.7–100) Moderate NPDR 86.4 (80.7–92.1) Severe NPDR 89.7 (85.8–93.6) PDR 94.8 (92.1–97.4) Direct comparison between digital colour and red-free imaging showed very good agreement in detecting and grading DR (weighted ƙ= 0.84;95% CI 0.80-0.88)	

Evidence Table : Effectiveness
Question : What is the effectiveness of hand held fundus camera

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
2) Yogesan K, Constable IJ, Barry CJ et al. Telemedicine Screening of Diabetic Retinopathy Using a Hand Held Fundus Camera. 2000; 6 (2): 219-223.	Study design: Diagnostic accuracy study Objective: To evaluate digital images of the retina from a handheld fundus camera (Nidek NM-100) for suitability in telemedicine screening of diabetic retinopathy. Methods: The same photographer took retinal images using both instrument at the same visit The Nidek images were digitized by a Fujix DF-10M digitizer The lossy compressed images and the photographs were presented separately in a random order to three ophthalmologist to grade them as good, acceptable, or unacceptable for diabetic retinopathy diagnosis. The digital images also evaluated for visible of microaneurysm (MA), blot hemorrhage (BH), hard exudate (CWS), new vessel elsewhere (NVE), fibrous tissue (FT) and photocoagulation scars (PHC).		49 eyes (25 consecutive patients) diabetic patients attending Lions Eye Institute Dilated using mydriacyl 1% and phenelephirine 10%.	Nidek NM-100 hand held fundus camera	Standard fundus camera (Zeiss)– table top	-	Result: Twenty four percent of digital images and corresponding photographs were assessed as being of good quality. 53%of digital images were acceptable of quality 16% of the digital images were graded as un acceptable quality There was poor agreement between the assessment of the photograph and digital image (k<0.30) Agreement between the ophthalmologist for assessment of the photographs (average correlation coefficient =0.8) Agreement between the ophthalmologist for grading of the digital images (average correlation coefficient =0.36) Average percentage of digital images and photographs where microstructures were identified grading results for 3 graders: MA: 81.3% BH: 63.3% EH: 42.3% CWS: 10.3% NVD: 4.7% NVE: 3.3% FT: 2.7% PHC: 21%	

	The photographer evaluated the ease of use of the camera. k values were computed for agreement between the assessment of the photographs and digital images.							

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3) K Yogesan, Henedrson C, Barry CJ, Constable IJ. Online eye care in prisons in western Australia. J of Telemed and telecare. 2001; 7(2): 63-64	**Study design:** cross sectional study **Objective:** -To provide specialist ophthalmic care to prisoners without transporting them to external hospital - to train prison medical officers and nurses to use equipment to screen prisoners for disease of the anterior segment or retina **Methods:** During first session, a Nidek NM100 hand held fundus camera was used to obtain retinal images in darkened room. In the second session, Use Nidek NM100D digital nonmydratic camera was used in three patients dilated eye using 1% tropicamide solution to examine the physiological lens.		N=11 patients 10 known diabetic 1 non diabetic Mean age (48; 30-82 years)	Nidek NM100 Nidek NM100D	No comparator	-	Both cameras were able to image the posterior pole, including the optic nerve head, with good resolution. The quality of retinal images obtained from either camera with or without dilation was considered either moderate or poor for diabetic retinopathy diagnosis but was adequate to assess optic disc cupping. It was not possible to identify any indication of diabetic retinopathy from retinal images.	

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4)Ting DSW, Kearney MTL, Kanasingam Y et al. Light and Portable novel device for diabetic retinopathy screening. Clin and Exp Pohthalmology.2012; 40 : e40-e46	**Study Design :** Diagnostic Accuracy Study **Objectives:** To validate the efficacy of an economical portable multipurpose ophthalmic imaging device, Eyescan (Opthalmic Imaging System) for diabetic retinopathy screening in the community **Methods:** Patients received pupil-dilating drops(2.5% phenylephrine and 0.5% tropicamide) They underwent 3 sets of retinal examination: i) Non-stereo colour retinal still photography (FF450 plus) ii) Non-stereo colour retinal still photography (Eyescan) iii) Slit lamp biomicroscopy examination with 78 diotptre lens by ophthalmolohist as reference standard Retinal still photography using Eyescan and FF450 plus was performed by a	1	From diabetic retinopathy screening clinic of Royal Perth Hospitals 136 consecutive patients (272 eyes) Mean ±SD age (53.9±15.3 years) Duration of diabetes (13.9±9.9 years) Hba1c (8.0±1.7%) Whites 74% (n=101) Asians 17% (n=23) Ethnic group 9% (n=12) 96 patients (71%) had Type 2 diabetes The best corrected visual acuity of 240 eyes(88%) was 6/6 or 6/9, 23 eyes (9%) was between 6/12 and	Eyescan	FF450 (Carl Ziess) table top	-	Eyescan graded by ophthalmologist Sensitivity : 93% (95% CI 84.9-97.1) Specificity : 98.2% (95% CI 94.3-99.5) Eyescan graded by medical officer Sensitivity : 91.7% (95% CI 83.2-96.3) Specificity : 94.7% (95% CI 89.9-97.4) FF450 graded by ophthalmologist Sensitivity : 95.1% (95% CI 87.0-98.4) Specificity : 98.8% (95% CI 95.4-99.8) FF450 graded by medical officer Sensitivity : 91.9% (95% CI 83.4-96.4) Specificity : 95.9% (95% CI 91.5-98.2) Sensitivity and specificity of images from both devices and graded by both readers increased to 100% technical failure rate of Eyescan : 8.5 technical failure rate of FF450 plus : 7% They were not statically significant (X2=0.23, d.f=1, P=0.63) failed retinal photographs captured by Eyescan caused by:	

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	medical officer (no previous experience in performing retinal still photography) and a retinal photographer (10 years experience) respectively. Three retinal fields (optic disc, macula and temporal views) were captured using both devices and the images were subsequently de-identified, randomized and interpreted by a consultant ophthalmologist and medical officer (competency : graded more than 1000 colour fundus photos of patients with diabetes) The images were graded on the basis of the presence of diabetic retinopathy signs(microaneurysms, retinal haemorrhages, hard exudates, cotton wool spots, venous beading, intraretinal microvascular abnormalities, new vessel formation and panretinal/vitreous haemorrhage) using international clinical diabetic retinopathy severity scale. They were classified as 'unacceptable, average, or excellent depending on their quality. They were graded as unacceptable if more than one third of it was blured or uninterpretable.		6/36 and 9 eyes (3%) was 6/60 or less Of the consecutively recruited eyes, nearly 35% hand diabetic retinopathy ranging from mild non-proliferative diabetic retinopathy. Nearly 15% (n=37) of eyes had previously received panretinal photocoagulation, and cataract were diagnosed in 28 eyes (10.3%) on the basis of slit lamp biomicroscopy examination. Almost 45% (n=118) of the patients had never undergone any diabetic retinopathy screening. Of the self-reported diabetes-related complications diabetic neuropathy (23%, n=62) and nephropathy (22%, n=60) were the leading complication.				39% (n=9) : eyes with cataracts 9% (n=2) : dark fundi 52% (12) : intolerance to bright flash failed retinal photographs captured by FF450plus caused by: 42.1 %(n=8) : secondary to cataract 10.5%(n= 2): dark fundi 47.4%(n=9): intolerance to bright flash The overall kappa statistic for diabetic retinopathy grading for Eyescan and FF450 plus were 0.93 and 0.95 for ophthalmologist and 0.88 and 090 for medical officer respectively The kappa coefficient for all diabetic retinopathy signs except macular oedeme based on the analysis of Eyescan and FF450 plus images by both readers, with reference to the slit-lamp The kappa coefficient for the ophthalmologist in detecting diabetic maculopathy using Eyescan and FF450 plus were 0.70 and 0.74, respectively whereas for the medical officer they were 0.71 and 0.76 respectively.	

Evidence Table : Effectiveness
Question : What is the diagnostic accuracy of hand held fundus camera

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5) Prakalapakorn SG, Wallace DK, Freedman S. Retinal Imaging in Premature infants using the Pictor noncontact digital camera. Journal of American Association for pediatric Ophthalmology and Strabismus. 2014; 18 (4): 321-326. Index medicus: Journal of AAPOS	**Study design:** Diagnostic accuracy Study **Objective:** i- to evaluate feasibility of using Pictor digital fundus camera to obtain high quality retinal images in prematurely born infants. ii- to evaluate the accuracy of grading the images for clinically significant posterior pole vascular changes (Pre plus or plus disease) compared to indirect ophthalmoscope. **Methods:** A retrospective review was performed on all retinal images of infants taken with the Pictor camera during routine Retinal of prematurity (ROP) rounds over a 6-month period from December 2011 to May 2012. A convenience sample of images was originally obtained for quality assurance purposes. The imager was a paediatric ophthalmologist who was using the Pictor camera for first time on prematurely born infants after reading the user's manual and practicing on undilated adults. During image collection, the imager attempted to obtain a focused still image of the infant retina which included an image of optic nerve.	2	48 premature infant with 96 eyes. Mean gestational age: 27 weeks (23,34) Mean birth weight: 872g (420,1480) Mean post menstrual age at examination: 38 weeks (31,47) Study was held in US .	Pictor digital hand held fundus camera		-	On clinical examination by indirect ophthalmoscopy during screening session: 6 (6%) of eyes had plus disease 7(7%) had pre-plus disease 83 (83%) had normal posterior pole Mean field of view for all eyes : 5.0 DD x 6.1DD Two ROP expert review on slide show of color and red-free images and evaluated for: 1. Quality (poor,fair,good) and number of gradable quadrant (0-4) of the picture as compared to cropped ICROP picture. **Result - Quality:** Grader 1 : 96% good to fair result Grader 2 : 97% good to fair result **Result - Number of gradable quadrant based on the adequate visibility at least 1DD length of a major vessel:** Grader 1 : 80% at least 3 gradable quadrants Grader 2 : 86% at least 3 gradable quadrants 2. Posterior pole disease classification A. Indirect ophthalmoscopy (reported plus disease) vs Pictor	

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	Most images were taken after the infant had examined by indirect ophthalmoscopy by one of 2 paediatric ophthalmologist trained in ROP screening. All photographs were obtained by one imager without the use of lid speculum while a nurse monitored infant from nearby. Most Imaging was performed with the baby swaddled and without additional person holding the infant. Pictor retinal images were obtained on a convenience sample of prematurely born infants. Images were reviewed by two ROP expert who masked to demographic and clinical examination. One of the authors create slide show where each slide included either color or red free image of right or left eye of an infant. Three images on each slide for each eye. 4 slides for each infant: i)1-3 color image right eye ii)1-3 color image left eye iii)1-3 red-free image right eye iv) 1-3 red-free image left eye at least one color and one red-free photograph taken of each eye at the same imaging session that included an image of the optic nerve. If eligible images were obtained at more than one imaging						image (reported pre plus or plus disease) Result Grader 1: sensitivity 100% (for both color and red- fee image), specificity 79% (80% for color, 79% for red-free image) Grader 2 : sensitivity 83% (for both color and red-free image) specificity 85% (87% for color , 83% for red-free image) B. Indirect ophthalmoscopy (reported pre-plus or plus disease) vs Pictor image (reported pre-plus or plus disease) Result Grader 1 : sensitivity 92% (for both color and red-free image) specificity86% (88% for color, 84% for red-free image) Grader 2: sensitivity 81%(77% for color, 85% for red-free image) specificity 90% (92% for color, 89% for red-free image) 3. Intergrader reliability for grading pre plus or plus disease was 95% (k= 0.9) 93% (k=0.8) for color image 91% (k= 0.7) for red free image	

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	session, the better quality images were selected to be included in the study Two ROP experts reviewed the slide show of color and red-free images independently and evaluated them for quality, number of gradable quadrants and posterior pole disease. Reference standard: indirect ophthalmoscope							

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6) Shah PK et al. Screening for retinopathy of prematurity- a comparison between binocular indirect ophthalmoscopy and Retcam 120. Indian J Ophthalmol. 2006: 54 (1): 35-8.	**Study design:** Diagnostic Accuracy study **Objective:** To compare the photographic screening for retinopathy of Prematurity (ROP) using Retcam 120 with binocular indirect ophthalmoscope (BIO) which is current gold standard. **Methods:** The infant pupils were dilated with a combination of 0.5% cyclopentolate and 2.5% phenylephirine. They were dilated 30-60min before the scheduled examination time. The Retcam 120 was used to photographically document the fundus features at the same visit. A series of photographs were taken to adequately capture the posterior pole and as much as possible, the periphery. Each series was saved and the images were transferred to a file devoid patient identifying information. All photographs taken from initial and follow up examinations were mixed for reading purpose and each session was identified by the randomization	2	27 (87 examinations) consecutive patients Mean birth weight :1468.88g (900,2050g) Mean gestational age: 32.33 weeks (28-36 weeks) Mean postconceptional age(PCA) at first Retcam examination : 35.63 weeks (33.2-44 weeks) Mean PCA at last Retcam evaluation :38.28 weeks (33.5-44 weeks)	Retcam 120			**Result:** Nine examinations with Retcam were false negative and Two were false positive. Sensitivity: 85.71% (95% CI: 84.1,87.32) Specificity: 91.66% (95% CI: 90.05,93.27) Positive Predictive Value : 96.43 (95%CI:94.81-98.04) Negative Predictive Value: 70.97% (CI 95%: 72.58, 69.35) Of the 54 examinations which clinical and Retcam examination both revealed the presence of ROP, 100% were located in zone 1 or zone 2. In Both Retcam and BIO; 10 examination judged fulminate ROP in zone 1 2 examination judged fulminate ROP in zone 2 7 examination judged stage 3 in zone 2 5 examination judged stage 2 in zone 2 2 examination judged stage 4b in zone 1 4 examination judged stage 3 in zone 2 by Retcam but fulminate ROP in zone 2 by BIO 2 examination judged stage 2 in zone 2 by Retcam but stage 1 in zone 2 by BIO 22 examinations were post laser Of the nine false-negative results (ROP by clinical examination, no ROP by Retcam), two were in zone 2 and seven in zone 3. Five had stage 1, four had	

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	number. The Retcam images were read in a masked manner by same examiner. The presence of laser photocoagulation scars if seen was noted. The distance between the optic nerve and fovea was measured for each posterior pole photograph to determine zone 1. If ROP seen the photograph, it was assumed to be located in either zone 1 or zone 2.						stage 2 and 2 had plus disease. Of the two false positive results (no ROP by clinical examination, ROP by Retcam) both were in zone 2 with stage 2 none had plus disease.	

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7) K Yogesan et al. Tele-opthalmolology screening for retinal and anterior diseases. J Telemed and Telecare. 2000; 6(1): 96-98	**Study design:** Diagnostic accuracy study **Objective:** To test DIO for use in the tele-ophthalmology screening for posterior and anterior segment disease **Methods:** Patients eye was dilated using tropicamide and phenelephrine hydrochloride Images of both eyes of each patient were obtained from digital indirect ophthalmoscope (DIO), Hand held Fundus Camera (HFC) Nidek NM-100 and table top stereo fundus camera (Nidek 3D-x) Images from the DIO and HFC were stored together with patient information using a laptop computer incorporating custom imaging software. Vertical horizontal cup disc ratio of the optic disc from DIO and HFC images graded as good, acceptable or unacceptable quality by an ophthalmologist. Gold Standard: Stereo fundus camera (Nidek 3D-x)	3	43 patients Average age: 60 years old Location: western Australia	Digital indirect ophtalmoscope (DIO) Hand held fundus camera (HFC) Nidek NM100	-	-	**Result:** Correlation coeffiecient calculated between vertical cup-disc ratios obtained : • DIO images compared with the gold standard was 0.80 • HFC and gold standard was 0.76 vertical cup disc ratio of images from HFC: • Specificity: 84% • Sensitivity: 100% vertical cup disc ratio of images from DIO: • Specificity: 87% • Sensitivity: 100% Overall poor quality images: • HFC : 8% • DIO : 30%n	