Diabetic retinopathy (DR) can be defined as a serious ocular complication of diabetes mellitus (DM). It can lead to impairment of vision and even blindness when not detected and treated on time. It is expected that one-third of diabetic individuals will eventually develop DR. Clinical signs such as micro-aneurysms, soft exudates, hemorrhages and hard exudates, occur in DR because damaged tiny blood vessels leak blood and fluid in the retina. DR can be divided into two main classes: non-proliferative DR which exhibits the above clinical signs and proliferative DR, a more advanced form of the disease involving the development of abnormal blood vessels. Symptoms of DR include double vision, blurred vision, difficulty perceiving colours, dark spots in the field of view and floaters. DR tends to occur in patients that have diabetes for a longer period of time and can remain asymptomatic until complicated signs such as vitreous haemorrhage or retinal detachment emerge. Risk factors for DR include prolonged duration of diabetes, elevated glycated haemoglobin, hypertension and use of insulin therapy. Individuals with diabetes will eventually be at risk of developing DR with rapid increment occurring in low and middle income countries. Thus there is likelihood that DR could become a major health challenge in various parts of the world. It is necessary that diabetic individuals undergo dilated retinal examination at least once a year as symptoms of DR do not occur at its early stages. Various ophthalmic procedures such as direct and indirect ophthalmoscopy, slit lamp biomicroscopy, and retinal fundus photography are used by clinical
experts to examine the retina for lesions associated with DR. In addition, the mydriatic seven field stereoscopic fundus colour imaging has been stated as the ideal technique for the screening of DR.12 Performing the above technique is complex, costly and time consuming and as such is not suitable for large-scale screening of DR.14,15 These challenges have led to the development of smartphone imaging systems as resourceful alternative for retinal examination in the past decade. The processing performance, connectivity and significant image resolution of smartphones have allowed them to be used in different professions including the medical field.16

Methods
The Google search engine was used to investigate the specifications of various smartphone imaging devices available for retinal examination. The information was obtained from the different companies’ websites and articles. Studies that have validated some of smartphone imaging devices for diabetic retinopathy screening were also retrieved for review. Keywords used for searching include fundus camera, retinal camera, retinal imaging, fundus imaging, smartphone fundus photography, diabetic retinopathy.

Smartphone imaging devices

20D condensing lens
This method initially introduced by Lord et al., 201017 involves holding a 20 D condensing lens before a dilated pupil of a patient. The camera of the smartphone will be placed along the pupillary axis of the patient. The camera and the lens will both be moved to find a good focus of the retina during video recording. Thereafter, the recorded video is played back and a screen shot of a good view of the retina is taken.18

D-Eye
Russo et al., 201519 created an inexpensive handy optical accessory that can be magnetically attached onto a smartphone. This device was derived from the basis of direct ophthalmoscopy and can be used to record videos and capture images of the retina. A smartphone application assists in reducing the intensity of the flash LED and alternating between automatic and manual focus. The system is usually placed at 1 cm from the eye of the patient and thereafter the acquired images or videos of the retina are saved either in the local storage or through a secure server. D-eye is compatible with iPhone models: 5, 5S, 6, 6S, 6 Plus, and 7 models.

iExaminer
The Welch Allyn iExaminer is made up of PanOptic ophthalmoscope, an application, an adapter, and an iPhone. The PanOptic Ophthalmoscope provides a 25-degree field of view without dilating the pupils. In order to acquire photographs of the retina, the optical access of the PanOptic Ophthalmoscope is aligned to the visual axis of the camera of the iPhone with the use of an adapter. The Application then enables the images to be stored in a patient file or emailed and printed. iExaminer is compatible with iPhone models: 4, 4S, 6, 6S and 6 Plus models.

oDocs nun
This is a next generation ophthalmoscope that has compatibility with a range of smartphones both Androids and iPhones. It is non-mydriatic as it works for pupil sizes as small as 2mm. It also has 30-degree field of view when the size of pupil is 4 mm with a dynamic focus of +20D to -20D

Volk iN view fundus camera
Volk iNview is an ophthalmic device that is made up of an application and an indirect ophthalmoscopic lens attachment. The application enables the device to automatically capture and select the best images of the retina. The device is mydriatic and capable of obtaining a wide 50-degree field of view to see the entire posterior pole in a single image. Thereafter the retinal images are stored with the data of the patient and can be easily transferred to a PC or Mac. Volk iN view is compatible with iPhone 5S, 6, 6S, and iPod Touch (Gen 6).

Remidio Fundus on Phone Non Mydriatic (FOP NM)
FOP NM is a smartphone-based system capable of capturing good quality retina photographs. This device uses high quality and precision optics to illuminate and capture retinal images at a working distance of 33cm. There is also a built-in application (Remidio fundus software) used for viewing and capturing retinal images in both mydriatic and non-
Table 1: Characteristics of different smartphone imaging systems

<table>
<thead>
<tr>
<th>Types</th>
<th>Developer</th>
<th>Need for dilation</th>
<th>Field of view</th>
<th>Image recorded</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 diopter condensing lens</td>
<td>Different developers</td>
<td>Yes</td>
<td>46 degrees</td>
<td>Yes</td>
<td>Varies</td>
</tr>
<tr>
<td>D-eye</td>
<td>D-eye srl</td>
<td>No</td>
<td>5-20 degrees</td>
<td>Yes</td>
<td>$400</td>
</tr>
<tr>
<td>iExaminer</td>
<td>Welch Allyn</td>
<td>No</td>
<td>25 degrees</td>
<td>Yes</td>
<td>$985</td>
</tr>
<tr>
<td>oDocs nun</td>
<td>oDocs Eye Care</td>
<td>No</td>
<td>15-40 degrees</td>
<td>Yes</td>
<td>$1,120</td>
</tr>
<tr>
<td>Volk iNview</td>
<td>Volk Optical Inc</td>
<td>Yes</td>
<td>50 degrees</td>
<td>Yes</td>
<td>$995</td>
</tr>
<tr>
<td>Remidio Fundus on Phone</td>
<td>Remidio Innovative</td>
<td>No</td>
<td>45 degrees</td>
<td>Yes</td>
<td>$8000</td>
</tr>
<tr>
<td>Non Mydriatic (FOP NM)</td>
<td>solutions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Different smartphone imaging devices used for diabetic retinopathy detection

<table>
<thead>
<tr>
<th>Studies</th>
<th>Smartphone Imaging system</th>
<th>Reference Standard</th>
<th>Kappa Agreement</th>
<th>Severity of DR</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ryan et al., 2015</td>
<td>20 diopter lens and iphone 5</td>
<td>7-field mydriatic fundus photography</td>
<td>Substantial</td>
<td>Any DR VTDR</td>
<td>50.0%</td>
<td>94.0%</td>
</tr>
<tr>
<td>Jamil et al., 2018</td>
<td>20 diopter lens and Samsung galaxy N9000</td>
<td>Slit-lamp biomicroscopy</td>
<td>Almost perfect</td>
<td>Any DR NPDR</td>
<td>89.5%</td>
<td>95.9%</td>
</tr>
<tr>
<td>Bose and Bose, 2018</td>
<td>20 diopter lens and iphone 7</td>
<td>-</td>
<td>Almost perfect</td>
<td>Any DR PDR</td>
<td>77.3%</td>
<td>99.1%</td>
</tr>
<tr>
<td>Russo et al., 2015</td>
<td>D-Eye and iphone 5</td>
<td>Slit-lamp biomicroscopy</td>
<td>Almost perfect</td>
<td>No DR</td>
<td>96.0%</td>
<td>90.0%</td>
</tr>
<tr>
<td>Sengupta et al., 2017</td>
<td>Remidio Fundus on Phone (FOP)</td>
<td>Topcon camera</td>
<td>-</td>
<td>Any DR</td>
<td>93.1%; 94.3%</td>
<td>89.1%; 94.5%</td>
</tr>
<tr>
<td>Prathiba et al., 2020</td>
<td>Remidio Fundus on Phone (FOP)</td>
<td>Zeiss FF450 fundus camera</td>
<td>Substantial</td>
<td>Any DR</td>
<td>75.2%</td>
<td>95.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Almost perfect</td>
<td>STDR</td>
<td>82.9%</td>
<td>98.9%</td>
</tr>
</tbody>
</table>
mydriatic pupil. A minimum of 45-degree field of view can give 10x magnification of the images of the retina. The device has a dioptrre correction of -30D to +30D and is compatible with smartphone camera of 8MP and above.

Studies on smartphone imaging systems for diabetic retinopathy detection
Ryan et al. 2015\(^1\) compared smartphone fundus photographs with retinal images from Zeiss FF450 Plus table top fundus camera to access its ability to detect DR. Three hundred diabetic patients were examined at the Eye Department at Dr. Mohan’s Diabetes Specialities Centre located in India. A 20D condensing lens and an iPhone 5 (Apple Inc., Cupertino, CA) with 3264 × 2488 pixels of the sensor of the camera was used for acquiring retinal images. Thereafter the images were graded by two independent retinal specialists. The sensitivity and specificity of smartphone fundus photography for the detection of any DR were 50.0% and 94.0% respectively. While the sensitivity and specificity of smartphone fundus photography for the detection of vision-threatening DR (VTDR; macular edema or severe non-proliferative DR or worse) were 59.0% and 100% respectively. There was moderate agreement for any DR (κ = 0.48) and substantial agreement for VTDR (κ = 0.71). Jamil et al. 2018\(^2\) examined 125 diabetic individuals (250 eyes) attending an ophthalmology department for the presence of DR. Two different procedures, the 20D and smartphone (Samsung galaxy N9000 with a resolution of 1920×1080) and slit lamp biomicroscopy were assessed by two independent ophthalmologists. The sensitivity and specificity for detecting DR was 89.5% and 99.5% respectively. The sensitivity and specificity for clinically significant macular oedema (CSME) was 82.6% and 99.6% respectively. There was almost perfect agreement between the two methods for detecting DR (κ = 0.92) and CSME (κ =0.87). Another study by Bose and Bose 2018\(^3\) evaluated retinal images from iPhone 7 (Apple Inc., Cupertino, CA, USA) smartphone and a 20D lens. Two investigators (trained optometrists) examined 36 patients with non-proliferative DR (NPDR). It was also observed that making use of smartphones for fundus imaging becomes easier when signs of NPDR such as microaneurysms, haemorrhages and venous beading were more in number. Smartphone Ophthalmoscopy using D-Eye attached to iPhone 5 (Apple Inc, Cupertino, California, USA) was compared with slit-lamp biomicroscopy in detecting the different grades of DR among 120 diabetic individuals.\(^4\) The range of sensitivity of D-Eye for detecting the different classes of DR was 55% to 96% while the range of specificity was 90% to 100%. There was substantial agreement for detecting any DR (κ= 0.78). The sensitivity and specificity of D-Eye for detecting CSME were 81% and 98% while the kappa value was 0.79 indicating almost perfect agreement. Sengupta, et al. 2017 \(^5\) compared mydriatic retinal photographs from Remidio Fundus on Phone (FOP) with Topcon fundus camera. Also, a clinical examination was conducted with a slit lamp biomicroscope and indirect ophthalmoscope by a retina specialist. Two independent retina specialists
classified the retinal images from 135 individuals (233 eyes) into different stages of DR. With retinal photographs from the Remidio FOP, the first and second grader reported a sensitivity of 93.1% and 94.3% respectively, in detecting any DR. With retinal photographs from the Topcon fundus camera, grader 1 and grader 2 reported a sensitivity of 92.6% and 94.9% respectively. The sensitivity of DR detection also increased from class 1 to 3 with both graders and cameras. The performance of Remidio FOP in the detection sight-threatening DR (STDR; severe non-proliferative DR or worse with macula oedema) in a tertiary eye care centre was evaluated by Prathiba et al. 2020. Fundus photography with Remidio FOP before mydriasis and with Zeiss FF450 table top fundus camera after mydriasis were obtained from diabetic individuals. The severity of DR was graded by ophthalmologists. The sensitivity and specificity for the detection of any DR were 75.2% and 95.2% respectively with Remidio FOP. While the sensitivity and specificity for the detection of STDR were 82.9% and 98.9% respectively with Remidio FOP. There was substantial agreement for detecting any DR (k = 0.67) and almost perfect agreement for detecting STDR (k =0.85) respectively.

**Discussion**
Mass-screening and regular ocular examination remains the only way for early detection and management of DR as this will help to reduce loss of vision by 50%. Conventional fundus cameras are not readily available for fundus examinations in developing nations in Africa because of the high cost of such devices. In addition, patients have to incur a significant amount of cost in order for retinal photography to be performed on them. Another factor is the bulky nature of these cameras can make it challenging to be used as first choice equipment for screening of DR. Smartphone fundoscopy will likely become a popular form of clinical examination in the eyecare sector in the near future. Hence its capability in detecting sight threatening conditions such as the presence of DR will go a long way in reducing visual impairment and blindness. This innovative form of retinal examination offers several advantages such as high level of screening of DR in regions with limited access to eye care and easy transmission of retinal images to clinical experts through the internet for diagnosis (Tele-health Care). Furthermore, Smartphone fundoscopy does not require constant power source like the conventional fundus camera.

Certain limitations have however been observed with smartphone imaging devices. One of them is that some of these devices are not compatible with android phones. In addition, the adapters made for iPhones are suitable for a particular iPhone model making it difficult to upgrade to newer versions of iPhones. Also, some of these devices have limited field of view which is not ideal in accurately detecting the clinical features of DR. In order to get a retinal image from a smartphone device comparable to images from a fundus camera, a properly dilated eye, clear ocular media, experienced examiner and cooperative individual are needed.

As improvements in technology will facilitate improved capabilities of smartphone fundoscopy, it is of upmost importance that privacy and data security measures are implemented by these new devices.

**Conclusion**
The application of smartphone fundoscopy in eyecare practice will lead to a more convenient form of diagnosis of various eye conditions including DR. Further researches comparing the effectiveness of using the above devices for DR detection across different populations should be conducted. This is in order to determine appropriate and affordable devices that can be easily acquired by clinicians especially in developing nations where the high cost of purchasing table top fundus camera remains a challenge.

**Acknowledgement:** None

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Smartphone Imaging Devices for Screening of Diabetic Retinopathy...


