Telemedicine: Validation of the use of iPhones to improve the detection rate of diabetic retinopathy in General Practice: the ADDITION study.

Background

Diabetic retinopathy is still the leading cause of blindness and visual impairment globally and associated with considerable costs for the health care system and the society. This is despite the fact that diabetic retinopathy is completely preventable either by primary prevention with strict control of metabolic risk factors, or by secondary prevention including systematic screening and treatment of early stages of retinopathy. While control of metabolic risk factors including HbA1c, blood pressure and lipids is generally good in hospital settings and general practices in Denmark, challenges remain with regard to the early detection of diabetic complications in general practice. The 2013/2014 report from the Danish Diabetes Database shows that in the different regions in Denmark, GPs have the result of a recent eye examination (<24 months old) only in 3%-6% of their adult diabetes patients, while the target for this indicator is 90%. Even if it is acknowledged that "It is still a problem that in many cases the result of the examination is not known to the GP"[1], in many cases it is also likely that no eye examinations have been performed at all.

These data indicate that there is a great potential to improve the quality of care of diabetic patients in general practice. Although there is no direct evidence regarding the main barriers for achieving a bi-yearly eye examination in >90% of diabetes patients treated in general practice, it seems that distance barriers in remote areas and limited access to ophthalmological specialist services may play a role.

Tele-medicine may offer a solution to this problem by separating the different components of the process and implementing each at the best location to ensure maximum participation and the most complete flow of information to all levels of care involved.

The current process for retinopathy screening of diabetes patients treated in general practice, consists of a referral to an ophthalmological clinic, where all parts of the process are handled:

- Image acquisition
- Evaluation of the retinal photograph by a trained grader
- Communication of the results to the GP

Further management decisions by the GP should then be based on the most up-to-date information.

Barriers seem to exist in getting patients to make an appointment at one of these central facilities, as well as in the communication of results back to the GPs.

We propose to investigate a model where the image acquisition takes place at the GP practice, in connection with a routine visit. The digital images are transferred to a central location and evaluated by a trained grader as in the current model. The results are then transferred back to the GP using the same

integrated system. This system requires for images of sufficiently high quality to be obtained in a distributed local setting, such as General Practice.

Acquisition of high-quality fundus images requires a combination of appropriate optics and illumination usually in the form of a condensing lens and a coaxial light source. This is part of the reason that a commercial fundus camera normally costs tens to hundreds of thousand dollars. The increasing availability of smartphones and the rapid advances in technology for capturing and sharing images have resulted in the expanding use of smartphones as a clinical-imaging device in ophthalmology. This application presents a unique opportunity for applications such as telemedicine. One small study has proved to capture high-quality fundus images with iPhones. The method uses the FiLMiC Pro videography app (on an iPhone 4 or 5) along with an ophthalmology-specific 20D lens, combined with a Koeppe lens, another standard tool in the field of ophthalmology. The use of smartphone-based retinal screening in general practice as part of the annual diabetes status visit has the potential to eliminate distance barriers and other barriers to receive care from specialists. However, while high-quality telemedicine is widely used and well established for centralised interpretation of conventional digital retinal photos, the validity of smartphone-based retinal screening has not yet been systematically tested.

We propose to use the 10-year clinical re-examination of the Danish arm of the ADDITION-trial to validate the quality of smartphone image acquisition for retinopathy screening. This is a first step in the development of a new workflow for decentralised retinopathy screening based in General Practice.

Aim:
To validate the diagnostic accuracy of taking retinal images using a handheld smartphone (with attached lens) compared to the current gold standard (retinography with dilatation) in patients with type 2 diabetes of approximately 10 year duration.

Outcomes:
The primary outcome is the concordance (Cohen's Kappa) between the diagnosis of the different types of diabetic retinopathy (exudates, proliferative retinopathy, non-proliferative retinopathy, macular oedema, other retinal pathology, any diabetes related retinopathy) based on the current gold standard and two modalities based on smartphone image acquisition:

- Gold Standard: conventional retinography with dilatation by a trained nurse
- Smartphone 1: smartphone retinography with dilatation taken by a trained nurse
- Smartphone 2: smartphone retinography with dilatation taken by an untrained health care professional

This protocol allows us to examine two different potential sources of variability and non-concordance: equipment, and level of training. Furthermore, the available data in the ADDITION database will allow us to examine whether

patient characteristics affect the accuracy of smartphone diagnosis of retinopathy. In secondary analyses we will assess whether, characteristics such as sex, age, glycaemic control, and type of diabetes treatment affect the level of agreement between the smartphone based diagnosis and the gold standard.

Population:
The study will be carried out amongst participants of the ADDITION trial who attend the 10-year clinical re-examination at Aarhus University Hospital (n=430) and Regionhospital Holstebro (n=239). These two centres have the necessary facilities.

Perspectives:
The protocol focuses exclusively on sources of variability at the level of image acquisition. Further sources of variability exist at the level of image evaluation and analysis; these can potentially be examined later based on the stored images but are outside the scope of this protocol.

The longer-term perspective of this project is to develop a decentralised system of retinopathy screening for diabetic patients treated in General Practice. The development of the image and data transfer systems that are needed for the practical implementation are also outside the scope of this project and will be developed once the validity of the image quality has been established.