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BAD MERGENTHEIM. Medical advances in diabetes care are far more likely to be driven by technical innovations than by new medicinal products, Professor Thomas Haak stressed when interviewed. One example is EyeArt, an AI-based eye-screening software application. How the screening works and why ophthalmologists and payers have nothing to fear.

? How has the Diabetes Center Bad Mergentheim been managing during the pandemic?

Professor Thomas Haak: So far very well, as due in part to compensation for empty beds we have not had to fill the Center to capacity. Since we work with the local Caritas Hospital, we could send our staff there and avoid putting them on short time. This has now come to an end. With increasing infection rates,

we will certainly have to reckon with positive cases here at the Center. For me, the worst part is the mutual mask requirement, meaning I can no longer look my patients properly in the face.

? In September, Germany’s Hospital Future Act for digitalization hospitals was passed. The aim is to facilitate increased digitalization. How will this benefit the Diabetes Center?

Prof. Haak: We will indeed benefit from this, as digitalization is the only way to keep up in the future. Over the next few years, medical advances in diabetes care will be achieved with technical innovations such as telemedicine rather than with medicines. In the interests of the



Professor Dr. Thomas Haak
Chief Physician Diabetes Center Mergentheim
image: zVg

Center, we will therefore take advantage of all the possibilities this law has to offer. We have long been working on digitalization concepts, having started by digitalization our documentation, for example, and now, as the next step, moving our daily operations into a digital environment.

? So how digital is the Diabetes Center right now compared with similarly structured medical centers?

Prof. Haak: We already have ward carts

“Medicine cannot be an analogue island”



The EyeArt AI-based eye-screening system requires neither dilatation nor an invasive intervention. In addition, the examination can be performed without having to visit an eye specialist. According to the manufacturer, the fully automated system delivers a PDF report in less than 60 seconds, grading diabetic retinopathy in accordance with international standards.

FDA APPROVAL FOR AI SYSTEM

EyeArt® received FDA approval in September 2020. According to Eyenuk, EyeArt is the first autonomous AI technology to receive FDA clearance that can be used to diagnose both mtmDR (more than mild diabetic retinopathy) and vtDR (vision-threatening diabetic retinopathy). The FDA-approved indications for use of EyeArt in the USA are: "EyeArt is indicated for use by healthcare providers to automatically detect more than mild diabetic retinopathy

and vision-threatening diabetic retinopathy (severe nonproliferative diabetic retinopathy or proliferative diabetic retinopathy and/or diabetic macular edema) in eyes of adults diagnosed with diabetes who have not been previously diagnosed with more than mild diabetic retinopathy. EyeArt is indicated for use with Canon CR-2 AF and Canon CR-2 Plus AF cameras in both primary care and eye care settings." Source: Eyenuk

on every ward that basically replicate our workstations. I therefore have full digital access to my own workstation from any hospital room, meaning I can view X-ray images, upload the latest results from the laboratory, retrieve the results from diabetic foot scans and discuss them directly with the patient. Yet a certain level of fatigue is already setting in. Managing everything on a monitor, video conferences all the time – it can be a strain. There is sometimes no substitute for personal contact. Yesterday I had an emotional chat with a long-time patient whose husband has just died in tragic circumstances. She told me about it at length; it was the kind of conversation where empathy and compassion are important and would not have been possible through a digital platform. There are many aspects of diabetes care, however, that I can manage very well in a digital setting, such as uploading patient data from the CGM device, meaning the patient need not travel long distances specially to visit the practice. We can discuss it by phone or video instead.

? You are the first person to use the EyeArt AI-based eye-screening application developed by the Californian startup Eyenuk. What have you learned so far and how do you finance the system?

"We want to use AI for diagnosis, not treatment"

Prof. Haak: The technology is based on artificial intelligence and in fact was originally used in military satellite systems. It also lends itself well to medical applications, such as here where we are examining the back of the eye. When I first read about EyeArt, our ophthalmologist had just retired, sadly without a successor. We have a lot of patients who have not seen an eye specialist in a long time and repeatedly complain that they can never get an appointment. Since then, we have used EyeArt rigorously for risk screening.

It is a very simple system, combining a fundus camera with Eyenuk's EyeArt software. We use it to compare our patients' latest images against hundreds of thousands of images already archived by Eyenuk. By correctly matching our findings with the archived pathological results we can achieve accurate risk stratification and tell the patient: something's not quite right, you need to see an eye specialist soon. Or even that everything's fine, there's no need to see an eye specialist due to your diabetes. Performing a large number of tests in a very short period of time is the clinical routine today. The servers are based in Europe. Nevertheless, we encode the images to guarantee data protection. Initially, the funding did not play a major role from my perspective as a doctor, as doing without this diagnostic method would have been terrible. Patient safety was my main concern. Our view now is that diabetic retinopathy is certainly a serious diagnosis that will increase the grading, so if I have a patient diagnosed with diabetes mellitus alone and an additional diagnosis of retinopathy, this will increase the DRG remuneration

rate, which in turn will quickly repay the costs of this system, even for hospitals. Relatively few of my patients out of a total of more than 4,000 are diagnosed with the condition, which is enough to finance the camera and the software. If I consider the number of patients under outpatient diabetic care who either fail to attend appointments with the ophthalmologist or turn up too late, then EyeArt belongs in the specialist diabetes clinics too. This is the only way to reduce the total of 2000 cases of blindness diagnosed every year. These cases could largely be avoided if the patients were promptly identified and received appropriate treatment from an ophthalmologist.

? The private and statutory health insurance companies don't appear to have caught on to this. There is still a lot of scepticism concerning artificial intelligence in medical science. Bearing this in mind, how important will the FDA approval for EyeArt last September be?

Prof. Haak: I believe that a lot of payers have not yet grasped the fact that we aim to use AI for the purpose of diagnosis, not treatment. I am assessing the risks in patients who need further treatment versus those who don't. In doing so I am relieving the burden on ophthalmologists and avoiding unnecessary referrals. EyeArt is more than a mere screening tool, as critics often claim. It is a diagnostic method with impressively high specificity and sensitivity in reading the scientific categories, delivering a result that is even more reliable than that obtained by an eye specialist! Without dilatation – the data simply speaks for itself.

? **Are diabetologists taking patients away from ophthalmologists with this early screening concept?**

Prof. Haak: Leading ophthalmologists I have spoken to do not regard this innovation as competition, as I am keeping patients – who need not even be seen by an eye specialist – out of their overflowing practices and creating resources for those who need them urgently and otherwise would not have even been discovered. As already mentioned, every specialist diabetes clinic should have this early screening system!

? **What would you recommend for you colleagues in independent practice?**

Prof. Haak: A remuneration code is needed for these practices. Without it, a lot of colleagues would not take it on. I can add that the system is easy to install, the examination can be performed by a medical assistant, it takes no more than five minutes, and only another two minutes before the result is available. This should be worth remuneration to the payers.

? **Why are the health insurers so reluctant to accept and appropriately reimburse AI methods? Surely, reducing the 2,000 cases of blindness a year should be both an incentive and an obligation?**

Prof. Haak: The Americans were clearly quicker to understand this. If the FDA, given its exacting requirements, has accepted the system and offers an appropriate remuneration rate of USD 50, I believe this is money wisely spent, especially if you consider the patients who will be spared a lot of suffering. Patients with diabetes are afraid of nothing more than the threat of going blind. But this shows how Germany is lagging far behind in the world of digitalization, despite all the rhetoric aimed at the Association of Statutory Health Insurance Physicians and medical fraternity.

? **What about the telematics infrastructure, how will you integrate EyeArt in the near future?**

Prof. Haak: I don't anticipate any

difficulties; it can be incorporated via an interface. Our computer automatically recodes the EyeArt findings into the recommendations for further action, which in turn correspond exactly with the recommendations in the guidelines of the German Diabetes Association.

? **A sensitive TI, the controversial EPR, digital health applications that nobody wants to prescribe, health authorities stuck in the digital stone age – there are so many negative reports at present about digitalization. What are your expectations?**

Prof. Haak: I think that the more every stakeholder recognises its benefits, the faster digitalization will advance. Medical science cannot survive as an analogue island while the entire world is being digitally transformed. In the long term, I am very optimistic!

*Interview: Manuel Ickrath
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