NICE advice

AI technologies for detecting diabetic retinopathy

Medtech innovation briefing
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Summary

- The **technologies** described in this briefing are EyeArt, RetinaLyze and Retmarker. They are used to detect diabetic retinopathy.
- The **innovative aspect** is that these technologies automate manual imaging grading.
- The intended **place in therapy** would be in addition to standard methods of detecting and grading diabetic retinopathy in people with diabetes. The UK National Screening Committee (UKNSC) noted this briefing should not be seen as a recommendation for use in diabetic eye screening programmes.
- The **main points from the evidence** summarised in this briefing are from 7 observational (retrospective and prospective) studies, including retinal images from 199,135 people with diabetes. They show that artificial intelligence (AI) technologies could be used to reduce the staff needed to identify and grade diabetic retinopathy in people with diabetes.

- **Key uncertainties** around the evidence are that the technologies have different levels of evidence without any randomised controlled trials to compare them, and it is not clear which technologies would integrate into the NHS best. EyeArt has more UK-relevant cost and clinical evidence.
- The mean **cost** per patient for RetinaLyze is £0.35 to £1.73 and for Retmarker it is £0.86 to £3.02 (both depend on the subscription level). The UK cost for EyeArt is not known; the US Medicare reimbursement for EyeArt is up to £39.93 per patient. Manual screening costs £4.79 per patient, and the overall cost of standard care is £9.92 per patient.

The technologies

EyeArt (Eyenuk), RetinaLyze (RetinaLyze System A/S) and Retmarker (Retmarker) use artificial intelligence (AI) technology to analyse retinal images to help diagnose diabetic retinopathy. The aim is to speed up and improve diagnosis. They could be used in national screening programmes and settings with limited expertise.

EyeArt is designed to work with most types of retinal cameras. The algorithm has been trained using data from over half a million people and 2 million retinal images. Colour fundus images are uploaded to the technology's GDPR-compliant cloud, which produces a PDF report in less than a minute. The technology grades the severity of diabetic retinopathy and reports results for each patient's eye on the NHS diabetic eye screening programme (NDESP) scale. It assesses the adequacy of the image at the time of photography. It also explains the reasoning behind the grading.

RetinaLyze can be accessed online or integrated into a healthcare centre's existing software systems. This technology needs someone to check the results, and claims detection of diabetic retinopathy but not diagnosis. This may change because the company has applied for class IIa CE marking.

Retmarker sends images securely to the data centre hosting the Retmarker technology and automatically removes images that show no signs of diabetic retinopathy lesions. It can be used on the healthcare centre's premises, and patients' data can be kept securely on just the centre's server if needed. The AI technology does not need individually identifiable patient data for its analysis. The company says that the technology can be used with most digital fundus cameras. The algorithm can incorporate patient history data to assess disease activity. Images with possible lesions and images of a high enough

quality to be graded are sent to a clinician for manual triage and grading. The technology allows users to select the analysis modules they need. It can be integrated into the healthcare centre's software systems.

Innovations

The companies claim these technologies speed up detection of diabetic retinopathy by automating the process of examining retinal images. Currently, trained retinal screeners examine each image to determine if there is diabetic retinopathy, which requires expertise and time.

The algorithms in the technologies were trained using a database of existing human-graded images. The algorithms were then tested against another set of images to fine-tune them for real-world use.

A potential benefit is that they could free retinal screeners to grade images at a higher level.

Current care pathway

Everyone aged 12 and over with diabetes has retinal screening using a retinal camera. The camera takes an image of the person's retina, which is then checked for changes. Screening is usually every year, but may be more frequent, depending on the findings from the first eye screening.

Diabetic retinopathy develops in stages over time. As it progresses, more frequent screening appointments (every 3 to 6 months) are needed. The condition may eventually lead to vision loss.

The following publications have been identified as relevant to the care pathways:

- NICE's guideline on diabetes (type 1 and type 2) in children and young people: diagnosis and management
- NICE's guideline on diabetes in pregnancy: management from preconception to the postnatal period
- NICE's guideline on type 1 diabetes in adults: diagnosis and management.

Population, setting and intended user

The technology is intended for people with diabetes aged 12 and over who have diabetic retinopathy screening. In 2018 an estimated 3,809,119 people had diabetes in the UK.

Screening takes place at GP practices, hospitals and opticians, and the technologies would be used by retinal screeners.

Policy implications

The UK National Screening Committee (UKNSC) is responsible for making recommendations on all aspects of screening programmes. This includes changes to tests that this technology would represent.

So this briefing should not be seen as a recommendation for use in diabetic eye screening programmes.

There are formal UKNSC evaluations of AI technologies happening in the diabetic eye screening pathways and formal recommendations will be made in due course.

Costs

Technology costs

EyeArt

The company has not provided the cost per patient for the UK. In the US, where EyeArt replaces human reading, Medicare is reimbursing healthcare providers up to £39.93 per patient for the EyeArt test. The reimbursement amount covers staff and infrastructure costs as well as the technology.

RetinaLyze

The service is available as a subscription and an organisation can buy a number of screenings upfront. Cost per patient varies depending on the number of patients, the hours the system is in operation and the subscription level. The cost is usually EUR 0.40 to EUR 2.00 (£0.35 to £1.73). There are additional costs for data management and storage,

and security and accessibility requirements. The AI algorithms rely on either a standalone web application running on a Windows PC with an internet connection or a PACS/EHR system integration. Both have monthly or yearly cost and server costs. Online training is included in the cost.

Retmarker

In the UK, the average cost per patient is tiered by purchased volume of episodes. These are bought upfront and must be used within 1 year unless otherwise agreed. The minimum number of episodes is 50,000 (unless otherwise agreed) at £3.02 per patient. The average cost per patient reduces with higher numbers of purchased episodes, down to a minimum cost per patient of £0.86. Server costs are not included. The cost of integrating the AI system into an existing provider depends on the scope and may partially or fully be covered by Retmarker.

Costs of standard care

The standard method of grading digital colour photographs in the UK uses trained human graders who meet specific quality standards, with multiple possible levels of grading and quality control checks.

The mean cost per patient for manual screening is estimated as £4.79, and the total cost per patient is £9.92, accounting for a mix of graders at different bands doing the test. Total costs include quality assurance, including monthly tests and training. These were based on a study by Tufail et al. (2016) and adjusted for inflation to 2020/21 prices at 3.5% per year in line with NICE recommendations.

Resource consequences

Trusts adopting these technologies should take into account that they each have different outputs, some of which may not be compatible with the grading system being used by the trust. Trusts should also consider the costs of the required level of service, system integration, secure data transfer, and data storage and management. The physical infrastructure will not need changing, apart from installing the technologies into local server infrastructures. Little to no training is needed to use them.

These technologies could be placed in different parts of the care pathway – as the first, second or arbitration grader – and reduce the workload of retinal screeners.

The technologies can analyse and triage images rapidly and speed up the screening process. Two of the technologies have a class IIa CE marking, so they have the potential to be used without human oversight. If adopted, the technologies could be cost saving for the NHS if they could replace human graders. Some of the costs saved could be used to train graders in optical coherence tomography (OCT) imaging. Many retinal scans happen in private opticians that are reimbursed by the NHS. Without further review, it's unclear how adopting these technologies would affect NHS resource use if they are primarily used in a private setting.

Regulatory information

EyeArt and Retmarker are CE marked class IIa medical devices. RetinaLyze is a CE marked class I (self-certified) medical device.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

People with type 1 diabetes are considered to have a disability, as is anyone with type 2 diabetes if their condition has a substantial, long-term, negative impact on their ability to carry out normal everyday activities. People who are registered blind or partially sighted are considered to have a disability, as are people not registered but whose sight loss has a substantial and long-term effect on their ability to carry out day-to-day activities. Disability is a protected characteristic under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This report summarises 7 observational studies; 3 were prospective and 4 retrospective. Four were in the UK, 1 in the US, 1 in Portugal and 1 in Italy. The studies included retinal images from 199,135 people with diabetes.

The clinical evidence and its strengths and limitations are summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The quality of the evidence supporting the technologies varies. None of the studies was a randomised controlled trial. Most of the evidence (5 of the studies) was on EyeArt. It had more evidence from different countries than the others and has the study with the largest sample size (n=101,710). There was UK evidence for all 3 technologies.

Five out of 7 studies were independent studies not involving the companies or their employees. Three of these were from the UK and received funding from the National Institute for Health Research (NIHR). One NHS-based study funded by the NIHR compared 3 diabetic retinopathy AI technologies: EyeArt, iGradingM and Retmarker. The second and third studies assessed EyeArt against human grading using images from the English NHS diabetic eye screening programme (NDESP).

Because the Ribeiro et al. (2015) study assessed Retmarker in a screening programme in Portugal, the study has a large sample size using the same constantly updating dataset.

Tufail et al. (2016)

Study size, design and location

An observational retrospective comparison study in the UK of 102,856 images from 20,258 people.

Interventions and comparator

EyeArt, iGradingM and Retmarker compared with manual image grading.

Key outcomes

Sensitivity for EyeArt was 94.7% (95% confidence interval [CI] 94.2 to 95.2) for any retinopathy, 93.8% (95% CI 92.9 to 94.6) for referable retinopathy and 99.6% (95% CI 97.0 to 99.9) for proliferative retinopathy.

Sensitivity for Retmarker was 73.0% (95% CI 72.0 to 74.0) for any retinopathy, 85.0% (95% CI 83.6 to 86.2) for referable retinopathy and 97.9% (95% CI 94.9 to 99.1) for proliferative retinopathy.

iGradingM classified all images as either 'disease' or 'ungradable', limiting the possible analysis.

The sensitivity and false positive rates for EyeArt were not affected by ethnicity, sex or camera type, but sensitivity declined marginally with increasing patient age.

Cost analysis estimated that the technologies became more expensive than human grading at a cost of £3.82 per patient for Retmarker and £2.71 per patient for EyeArt.

Strengths and limitations

Strengths: the study had a large sample size, and all 3 technologies evaluated the same images. This independent study was done in the UK in the NDESP. The cost calculations are relevant to the NHS.

Limitations: the cost analysis was limited because the study was not randomised.

Heydon et al. (2021)

Study size, design and location

A prospective study in the UK of 30,405 screening episodes from people with diabetes from 3 English diabetic eye screening programmes.

Intervention and comparator

EyeArt v2.1.0 compared with human grading.

Key outcomes

Sensitivity of EyeArt was 95.7% (95% CI 94.8 to 96.5) for referable retinopathy (human graded as ungradable, referable maculopathy, moderate to severe non-proliferative or proliferative). This comprises sensitivities of 98.3% (95% CI 97.3 to 98.9) for mild to moderate non-proliferative retinopathy with referable maculopathy, 100% (95% CI 98.7 to 100) for moderate to severe non-proliferative retinopathy and 100% (95% CI 97.9 to 100) for proliferative disease. EyeArt agreed with the human grade of no retinopathy (specificity) in 68% (95% CI 67 to 69), and 54.0% (95% CI 53.4 to 54.5) when combined with non-referable retinopathy.

Strengths and limitations

Strengths: this was a prospective independent study with NIHR funding and a large sample size from 3 real-world screening programmes. The authors have reported detailed methods of the processes and protocols. No limitations identified.

Olvera-Barrios et al. (2021)

Study size, design and location

A real-world study using retrospective data from a UK national screening programme including 1,257 adults.

Intervention and comparator

EyeArt V.2.1.0 using true-colour, wide-field confocal scanning images and standard fundus images in the English NDESP. Imaging with mydriasis (two-field protocol) used the EIDON platform (CenterVue, Padua, Italy) and standard NDESP cameras compared with a human grade of standard NDESP images.

Key outcomes

Sensitivity estimates for retinopathy grades were: (EIDON images) 92.27% (95% CI 88.43 to 94.69) for any retinopathy, 99% (95% CI 95.35 to 100) for vision-threatening retinopathy and 100% (95% CI 61 to 100) for proliferative retinopathy; (NDESP images) 92.26% (95% CI 88.37 to 94.69) for any retinopathy, 100% (95% CI 99.53 to 100) for vision-threatening retinopathy and 100% (95% CI 61 to 100) for proliferative retinopathy.

One case of vision-threatening retinopathy (R1M1) was missed by the EyeArt when analysing the EIDON images but identified by the human graders. The EyeArt identified all cases of vision-threatening retinopathy in the NDESP images.

Strengths and limitations

Strengths: this was an independent study with no support from or affiliation to the company. The quality of reporting was high, and the context relevant, being from a screening programme in the UK. The risk of bias was low because it included a representative sample, published a prospective protocol, used masked graders, and sent anonymised data to EyeArt. The vendor was not allowed access to the software or the dataset during the study period.

Limitations: the analysis was based on retrospectively collected data. In a service evaluation study of the EIDON confocal scanner with human grading, it was evidenced that the EIDON images were able to visualise high-risk retinopathy features missed by the NDESP images. Because of this, the selection of the reference standard can be debatable.

Demography, duration of diabetes, ethnicity, time taken for imaging with each imaging platform and pupillary diameter for this dataset were not analysed. There might be a 'black-box' issue (meaning there is a lack of transparency about how the output was calculated) with the EyeArt and the processing of EIDON images because the reference parameters or data points used by the software might not be the same as the ones used in standard 45-degree colour fundus images, so there could be differences in grading. Further work is needed to define if the wide-field true-colour images provide advantages in terms of diagnostic accuracy with the EyeArt software.

Ribeiro et al. (2015)

Study size, design and location

Prospective study of a screening programme in Portugal including 45,148 people (89,626 eyes) with type 1 and 2 diabetes.

Intervention and comparator

RetmarkerSR first, and if disease detected, then human grading; no comparator.

Key outcomes

The screening programme images were analysed in a central reading centre using first an automated disease or no disease analysis and then human grading of the disease cases. Results were: 71.5% no retinopathy, 22.7% non-proliferative retinopathy, 2.2% maculopathy, 0.1% proliferative retinopathy and 3.5% not classifiable. The authors concluded that using an automated system could reduce the need for human grading by 48.42%.

Some eyes could not be classified (3,132 [3.5%]) because of poor image quality as a result of cataract, myosis, or because the patient was unable to collaborate. The number was similar to the previous screening programme without implementing AI.

The grader identified only 11 cases out of the 3,287 (0.3% of quality control cases, 0.02% of total patients) as having referable retinopathy pathology (false negatives). None of these cases was proliferative retinopathy.

The intra-grader analysis showed an agreement of 98.92% and a sensitivity and specificity of 100% and 99.51%, respectively. The inter-grader analysis showed an overall agreement of 96.65%, with a sensitivity and specificity of 97.52% and 98.55%, respectively.

Strengths and limitations

Strengths: the study reports on a large dataset from a regional screening programme that shows the prevalence of diabetic retinopathy grades. The methods and the results were well described. To check the safety of non-disease cases, a random sample was sent to a masked human grader for double-checking. For quality control, a random sample of all images was graded by a second masked human grader.

Limitations: there was no control group. The annual follow-up re-screening results for non-disease cases were not reported to assess the safety and risk of false negative cases. Two of the authors are affiliated with the company.

Sarao et al. (2020)

Study size, design and location

A prospective study in Italy of 165 adults (330 eyes; 660 retinal images) with type 1 and 2

diabetes attending a routine annual visit at an ambulatory surgical centre.

Intervention and comparator

Conventional flash fundus camera image for EyeArt v2.1 compared with LED confocal scanner image for EyeArt v2.1.

Key outcomes

Sensitivity, specificity, and area under the curve (AUC) for flash fundus camera were 90.8% (95% CI 85.0 to 94.9), 75.3% (95% CI 68.0 to 81.7) and 0.830 (95% CI 0.78 to 0.87) respectively; and for LED confocal scanner were 94.1% (95% CI 89.1 to 97.3), 86.8% (95% CI 80.7 to 91.6), and 0.905 (95% CI 0.87 to 0.93) respectively. The difference between AUCs was 0.0737 (95% CI 0.0263 to 0.121; p=0.0023).

The receiver operating characteristic curves for referable diabetic retinopathy show that the AUC was higher with the confocal scanner (z statistic 3.047, p=0.002), implying a better grading accuracy.

Images from 8 eyes (2.4%) were classified as ungradable by the human graders so were not considered for comparison with the automated assessment. The reasons were mainly around inadequate field capture (5 eyes) and the presence of significant media opacities (3 eyes).

Strengths and limitations

Strengths: the study reported the imaging protocol and a detailed and high-quality methods and limitations section to avoid bias. After masking the identity of the patient, retinal images were submitted to the Eyenuk cloud. The authors were not affiliated with the company, so this is an independent study.

Limitations: the sample size is relatively small, and the proportion of patients with pre-proliferative retinopathy is higher than what is typically reported in a screening programme. The EyeArt software was largely trained with conventional flash fundus cameras, which might influence the results obtained with the scanner. Most evaluations of automatic diagnosis of eye diseases focus on a binary classification. In contrast, in a clinical setting, patients typically suffer from several different retinal conditions that reduce the algorithm's accuracy as the number of retinal diseases increases.

Bhaskaranand et al. (2019)

Study size, design and location

A retrospective study in the US of 850,908 fundus images from 101,710 consecutive participant visits in people with diabetes.

Intervention and comparator

EyeArt; no comparator.

Key outcomes

Automated analysis of the entire dataset (850,908 images) was completed in less than 48 hours; 4.9% of visits were excluded from the analysis because of insufficient information. Of those included, 0.9% were flagged as being unscreenable by the technology and were referred to a specialist. The screening sensitivity of the technology was 91.3% (95% CI 90.9 to 91.7) and specificity was 91.1% (95% CI 90.9 to 91.3). The positive predictive value was 72.5% (95% CI 71.9 to 73.0), and the negative predictive value was 97.6% (95% CI 97.5 to 97.7). The AUC was 0.965 (95% CI 0.963 to 0.966).

Strengths and limitations

Strengths: the study included a large consecutive patient population and the technology assessed retinopathy in 99% of patient visits. Although the study did not include a comparator, specialist assessment of fundus images was used as a standard. The study recruited consecutive patients from over 400 primary care centres to reduce selection bias.

Limitations: the lead author is an employee of Eyenuk. Patient demographic data, such as age and time since diabetes diagnosis, were not collected.

Bouhaimed et al. (2008)

Study size, design and location

A retrospective UK study of 400 fundus images from 192 eyes of 96 people with diabetes.

Intervention and comparator

RetinaLyze, expert grading of images; no comparator.

Key outcomes

The technology detected red lesions with a sensitivity of 82%, a specificity of 75%, a positive predictive value of 41%, and a negative predictive value of 95%. The technology detected red and bright lesions with a sensitivity of 88%, a specificity of 52%, a positive predictive value of 28%, and a negative predictive value of 95%.

Strengths and limitations

Strengths: this is an independent study and was done in the UK.

Limitations: study data were collected from 2002 to 2004 and clinical practice is likely to have changed.

Sustainability

The companies claim using AI to screen digital fundus images could reduce environmental impact because less time and fewer staff are needed to process the images. There is no published evidence to support this.

Recent and ongoing studies

- Pilot assessment of EyeArt as an automated diabetic retinopathy screening tool. ClinicalTrials.gov identifier: NCT03078231. Status: completed. Indication: diabetic retinopathy. Devices: EyeArt. Last updated: July 2018. Country: US.
- Assessment of EyeArt as an automated diabetic retinopathy screening tool. ClinicalTrials.gov identifier: NCT03112005. Status: completed. Indication: diabetic retinopathy, diabetic eye problems, and diabetic macular oedema. Devices: EyeArt. Last updated: July 2018. Country: US.

No ongoing or in-development studies were identified for the other technologies.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 4 experts were familiar with the technologies, but none of them had used them. Two of the experts were aware of their use in screening programmes in Scotland and Singapore.

Level of innovation

Two experts were not aware of any other relevant technologies. The other 2 experts reported that there are other similar companies with AI technologies for diabetic retinopathy, but they have not published their research or have not received CE marking yet.

Potential patient impact

All experts agreed that the technologies could be applied to all people with diabetes aged 12 and over as per current protocol.

All 4 experts agreed using these technologies has potential benefits for the patients. One explained that early detection of sight-threatening diabetic retinopathy by these technologies would result in earlier treatment and potentially saving sight. People with diabetic retinopathy can be at a higher risk of cardiovascular disease and stroke, so early intervention could prevent them becoming a problem. Potentially, other non-diabetes related serious illnesses could be diagnosed from the retinal images. One expert said that because these technologies can be used for any eye and for patients from different ethnicities, genders, ages and duration of diabetes, they serve a wide range of patients. Another expert mentioned reducing hospital visits as a benefit if people are able to be screened at home, adding that these systems will help people unable to get to hospital because of reduced mobility.

Potential system impact

Three out of 4 experts said that these technologies are useful and could be used to save time and resources. They also said they could improve reproducibility and consistency

across practices and provide quality assurance for screening programmes. Two of the experts suggested that these technologies should be used in screening programmes. All 4 experts agreed that these technologies may be used alongside human graders and standard care, and may replace at least primary level human grading. Two experts said that AI might gradually replace secondary and arbitration level human grading as well.

Each expert reported different benefits of using AI systems, including real-time reporting of results to diagnosis and reduction in waiting time for patients, less delay in follow-ups, reduction in human contacts with the possibility of home monitoring, and increased efficiency of screening programmes, and cost savings for the NHS. One of the experts noted that implementing these technologies might at first lead to increased costs, but in the long term, they can be cost saving. However, they said there should be an ongoing economic evaluation of these technologies as further developments are anticipated. One expert said using AI technologies will lead to less dependency on scarce staff.

One of the experts believed that these systems could reduce the workload and the need for staff. However, 2 experts highlighted that, because the systems can grade constantly, the possible higher detection rate of diabetic retinopathy could lead to increased referrals to hospital eye service. Another expert said that the current pathway could be shortened by using AI systems. They said that experienced human graders could instead better manage sight-threatening retinopathy, potentially leading to better clinical outcomes. One expert said using these systems is unlikely to change the current pathway or clinical outcomes. The grading protocol determines the outcome, so changes to protocols in the future may lead to fine-tuning of the algorithms used by these systems. Two experts also said that camera hardware changes may affect the performance of these technologies and shift the setting from clinic to home. Therefore, the benefits to the healthcare system depend on where the technologies are implemented in the clinical pathway. They could add an extra layer of quality assurance to the graders. Almost 90% of negative cases received only 1 human grading. Adding these systems would mean all images were graded by the AI system and at least 1 human grader.

Three experts said better and secure cloud storage and data transferring facilities would be needed, which may need investment. One of the experts said that none of the systems had been integrated into existing patient management systems. Two experts said staff needed training in using web-based and data-based technologies. One expert mentioned a lack of trust in the systems, while another brought up the potential to miss some pathologies if human graders are replaced. One expert said ownership of errors was a potential barrier, and one said governance issues was another.

General comments

Potential usability issues mentioned by the experts were:

- the use of a different grading classification
- appropriate integration of the AI system into existing systems
- smooth data transfer
- staff training and testing how the technologies perform when screening high volumes of images, similar to what would be expected in routine practice
- camera type and cost
- the number of images that need to be taken (and so time)
- the need for dilated pupils.

The experts said more research was needed on existing real-world datasets (retrospectively), studying false positive and false negative cases, and tests in screening programmes (prospectively). They also recommended continuous performance audits and potential upgrades and assessment of systems' ability to identify all major eye diseases, not just diabetic retinopathy. One of the experts said that none of the companies reported results the same way so pre-proliferative and proliferative features could be different across platforms.

Expert commentators

The following clinicians contributed to this briefing:

- Professor David Raymond Owens, professor of diabetes, Swansea University Medical School. Provides advice to Northgate Public Services relating to their 7 diabetic retinopathy screening services in England.
- Dr Rebecca Thomas, senior research officer (retinopathy), informatics lead, Diabetes Research Unit Cymru; co-programme director MSc Diabetes Practice, Swansea University. Did not declare any interests.

- Professor Richard Gale, consultant ophthalmologist, York Teaching Hospitals NHS Trust. His research group has received a small grant from Bayer UK to pump prime an AI tool development programme for macular degeneration. There is no interest in diabetic screening or any of the companies listed.
- Dr Ateeq Syed, site lead – diabetes, diabetes foot lead, Heartlands Hospital, University Hospitals Birmingham. Did not declare any interests.

Development of this briefing

This briefing was developed for NICE by King's Technology Evaluation Centre (KiTEC). The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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