NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Diagnostics consultation document

Artificial intelligence (AI) software to help clinical decision making in stroke

The National Institute for Health and Care Excellence (NICE) is producing guidance on using software with artificial intelligence derived algorithms for analysing CT brain scans in the NHS in England. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the evidence (the diagnostics assessment report and the diagnostics assessment report addendum).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for guidance to the NHS?

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on people with a particular disability or disabilities.

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Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on software with artificial intelligence derived algorithms for analysing CT brain scans. The recommendations in section 1 may change after consultation.

After consultation, the committee will meet again to consider the evidence, this document and comments from the consultation. After considering the comments, the committee will prepare its final recommendations, which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see the diagnostics assessment programme manual.

Key dates:

Closing date for comments: 14 April 2022

Second diagnostics advisory committee meeting: 26 April 2022

1 Recommendations

NICE is aware that companies are reviewing their CE marking in response to changing regulations and advances in digital health technologies.

1.1 There is insufficient evidence to recommend the routine use of artificial intelligence (AI) software to help clinical decision making in stroke (see sections 1.2 to 1.4). Further research is needed on the technologies to understand their diagnostic accuracy and impact on clinical outcomes (see section 1.5) when used alongside clinician interpretation.

1.2 There is insufficient evidence to recommend the routine use of the following technologies for guiding thrombolysis treatment decisions for people with suspected acute stroke using a non-enhanced CT scan:

- Accipio (MaxQ AI)
- Aidoc (Aidoc)
- Biomind (Biomind.ai)
- Brainscan CT (Brainscan.ai)
- CINA Head (Avicenna)
- e-Stroke (Brainomix)
- Neuro Solution (Nanox.AI)
- qER (Qure.ai)
- RapidAI (Ischemaview)
- Viz (Viz.ai)

1.3 There is insufficient evidence to recommend the routine use of the following technologies for guiding mechanical thrombectomy decisions for people with an ischaemic stroke using CT angiography:

- Aidoc (Aidoc)
- CINA head (Avicenna)
- e-Stroke (Brainomix)

- RapidAI (Ischemaview)
- Viz (Viz.ai)

1.4 There is insufficient evidence to recommend the routine use of the following technologies for guiding mechanical thrombectomy treatment decisions for people with ischaemic stroke using CT perfusion after a CT angiography brain scan:

- Cercare (Perfusion) (Cercare Medical)
- CT Perfusion 4D (GE Healthcare)
- e-Stroke (Brainomix)
- icobrain ct (icometrix)
- RapidAI (Ischemaview)
- Viz (Viz.ai)

1.5 Further research is recommended (see section 4) to:

- assess how using AI-software technologies alongside clinician interpretation of CT brain scans affects diagnostic accuracy in identifying and classifying stroke
- understand how reliably the AI-software technologies work in clinical practice when used alongside clinician interpretation
- understand how using AI-software technologies alongside clinician interpretation in the diagnostic pathway affects time to treatment in ischaemic stroke
- assess how using AI-software technologies alongside clinician interpretation in the diagnostic pathway affects clinical outcomes, including level of disability (both apparent and non-apparent) after stroke.

Why the committee made these recommendations

Stroke adversely affects quality of life for many people who survive it. Faster access to treatment could improve clinical outcomes and so quality of life after stroke. AI-software technologies used alongside clinician interpretation of CT brain scan

images could guide and speed up decision making in stroke, for example decisions on thrombolysis and thrombectomy treatment.

Clinical evidence on the AI-software technologies is limited in quantity and quality. There is no evidence on their diagnostic accuracy when used alongside clinician interpretation. Studies on their use in clinical practice give results only for people who had a positive test result and treatment. So, it is unclear how using the technologies affects clinical outcomes, particularly for people who may not have the correct treatment because their diagnosis has been missed (false negatives). These studies also suggest that people had faster access to treatment after using the software technologies, but it is unclear if this is an effect of using the software.

The lack of data on diagnostic accuracy and clinical outcomes means that the cost effectiveness of using AI-software technologies in suspected acute stroke cannot be determined, so they cannot be recommended for routine use in the NHS. Further research is needed.

2 The diagnostic tests

Clinical need and practice

2.1 Stroke is a serious life-threatening medical condition that happens when blood supply to a part of the brain is severely compromised. More than 100,000 strokes happen in the UK every year. The average age for stroke across the UK varies, with a median age of 77 (interquartile range 67 to 85 years). A quarter of strokes happen in people of working age. Stroke is a leading cause of disability and one of the most common causes of early death in the UK.

2.2 Treatment of stroke depends on the cause, length of time the blood supply to brain has been compromised and the severity of the damage caused by the stroke. In ischaemic stroke (the most common type), when blood supply to the brain gets blocked by a clot, treatments aim to restore blood flow by dispersing the clot with an intravenous injection of a clot-busting drug (thrombolysis) and mechanically removing the clot

(thrombectomy). Thrombolysis needs to be started within 4.5 hours of onset of stroke symptoms and thrombectomy should be offered as soon as possible to people who were last known to be well within the last 6 hours or considered as soon as possible for people who were last known to be well between the last 6 and 24 hours. In the less common type of stroke, intracerebral haemorrhage, when a weakened blood vessel in the brain bursts and blood leaks into soft brain tissues, these treatments would be harmful and should not be offered.

2.3 CT brain scans are used to help guide treatment choice. In people with a suspected acute stroke, a non-enhanced CT scan is used first to determine if the stroke is ischaemic so that thrombolysis can start. In people with confirmed ischaemic stroke, a CT angiography is then used to confirm the presence of a clot and to assess if it is a large vessel occlusion (a clot in a location where it could be removed by thrombectomy). When the impact of stroke is likely to be more severe because the blood supply to the brain has been reduced for a longer time (between 6 and 24 hours), CT perfusion is used to assess if there is the potential to salvage brain tissue by doing a thrombectomy.

2.4 Software with artificial intelligence (AI)-derived algorithms can be used to analyse CT brain scan images from people with suspected acute stroke to detect and report irregularities. The result of this analysis is intended to support the scan review and reporting by a trained healthcare professional. By identifying, quantifying and highlighting stroke-related changes in the brain, the AI-derived algorithms may support clinical decisions about suitability of an appropriate time-sensitive treatment. Using the software in the radiology pathway may lead to quicker review of scans by a multi-site clinical team, improved decisions about treatment, expedited patient transfer, faster access to the correct treatment and improved patient outcomes. Some software has features that can prioritise the review of stroke CT scans.

The interventions

Accipio (MaxQ AI)

2.5 Accipio is a software with AI-derived algorithms. It detects and analyses intracranial haemorrhage on non-enhanced CT brain scans and large vessel occlusions on CT angiography brain scans. The cost of Accipio is not known.

Aidoc (Aidoc)

2.6 Aidoc is a software platform that includes AI-derived stroke-related algorithms Aidoc ICH and Aidoc LVO. Aidoc ICH detects intracranial haemorrhage on non-enhanced brain CT scans. Aidoc LVO detects large vessel occlusions on CT angiography brain scans. The platform also includes Aidoc Mobile, a communication component to help communication between healthcare professionals in the stroke pathway. The manufacturer estimates that the licence fee for Aidoc for centres doing up to 45,000 CT brain scans per year is around £24,800 per year. For centres doing more than 45,000 CT brain scans per year, the licence fee is estimated as to be around £32,900 per year.

As well as the individual software package, Aidoc has partnered with icometrix (see section 2.13) for a 'stroke solution' (AIDOC ICH for detecting intracranial haemorrhage on non-enhanced CT brain scans, AIDOC LVO for detecting large vessel occlusion on CT angiography brain scan and icobrain ctp is used for CT perfusion brain scan analysis in ischaemic stroke).

Biomind (Biomind.ai)

2.7 Biomind is a software that includes AI-derived algorithms for detecting, locating and assessing the severity of intracerebral haemorrhage on non-enhanced CT brain scans. The cost of Biomind is not known.

Brainscan CT (Brainscan.ai)

2.8 Brainscan CT is a software with AI-derived algorithms. It detects and locates intracerebral haemorrhage and acute ischaemic stroke on non-enhanced CT brain scans. The cost of Brainscan CT is not known.

Cercare (Perfusion) (Cercare Medical)

2.9 Cercare (Perfusion) is a software with AI-derived algorithms for CT and MRI brain scans. It uses data on tissue oxygenation to provide identification of suspected stroke lesions. It provides an overview of brain tissue status on CT perfusion brain scans. The cost of Cercare (Perfusion) is not known.

CINA head (Avicenna)

2.10 CINA head is a software platform that includes AI-derived algorithms CINA-ICH, CINA-LVO and CINA-ASPECTS. CINA-ICH detects intracranial haemorrhage on non-enhanced CT brain scans and prioritises them on the radiologist's worklist. CINA-ASPECTS analyses non-enhanced CT brain scans to help characterise early ischaemic brain tissue injury. CINA-LVO detects and prioritises the review of large vessel occlusions on CT angiography brain scans. Assuming a minimum of 1,000 scans a year, cost ranges from around EUR 7.08 per scan for centres doing up to 5,000 CT brain scans a year to around EUR 5.27 per scan for centres doing over 20,000 CT brain scans a year.

CT Perfusion 4D (GE Healthcare)

2.11 CT Perfusion 4D is a software with AI-derived algorithms. It provides an overview of brain tissue status on CT perfusion brain scans. The cost of CT Perfusion 4D is not known.

e-Stroke (Brainomix)

2.12 e-Stroke is a software platform with AI-derived algorithms e-ASPECTS, e-CTA and e-CTP. e-ASPECTS detects acute ischaemic stroke on non-enhanced CT brain scans. e-CTA detects and locates large vessel

occlusions on CT angiography brain scans. e-CTP analyses CT perfusion brain scans to provide information about brain tissue status. The cost of the software licence for a comprehensive stroke centre is around £30,000 per year and for an acute stroke centre around £15,000 per year.

icobrain ct (icometrix)

2.13 icobrain ct is a software platform that includes AI-derived algorithm icobrain ctp for analysing CT perfusion brain scans to determine the presence of potentially salvageable brain tissue in ischaemic stroke. The cost of icobrain ct ranges from around £20,000 to around £45,000 per year depending on volume. As well as the individual software package, icometrix has partnered with Aidoc on a 'stroke solution' (see section 2.6).

Neuro Solution (Nanox.AI)

2.14 Neuro Solution is a software with AI-derived algorithms. It detects intracranial haemorrhage on non-enhanced CT brain scans. Until November 2021, this technology was known as Zebra-Med (Zebra Medical Vision). The cost of Neuro Solution is not known.

qER (Qure.ai)

2.15 qER is a software with AI-derived algorithms for detecting intracerebral haemorrhage and areas of brain tissue death (infarct) on non-enhanced CT brain scans. The cost of qER is not known.

RapidAI (Ischemaview)

2.16 RapidAI is a software platform that includes AI-derived stroke-related algorithms Rapid ICH, Rapid ASPECTS, Rapid CTA, Rapid LVO and Rapid CTP for analysing CT brain scans. Rapid ICH detects intracerebral haemorrhage on non-enhanced CT brain scans. RAPID ASPECTS assists in assessing the extent of disease on non-enhanced CT scans from people who have ischaemic stroke caused by a large vessel occlusion. Rapid CTA and RAPID LVO detect and locate large vessel

occlusions on CT angiography brain scans. Rapid CTP analyses CT perfusion brain scans to give information about salvageable brain tissue. RapidAI is provided on an annual subscription fee basis. An average cost per centre is around £20,000 per year.

Viz (Viz.ai)

2.17 Viz is a software platform that includes AI-derived stroke-related algorithms Viz ICH, Viz LVO and Viz CTP. Viz ICH detects intracranial haemorrhage on non-enhanced CT brain scans. Viz LVO detects large vessel occlusions on CT angiography brain scans. Viz CTP analyses CT perfusion brain scans to provide information about salvageable brain tissue. The cost of the software for a comprehensive stroke centre is in the region of around £40,000 to £55,000 per year and for a primary stroke centre around £20,000 to £30,000 per year.

The comparator

CT brain scan review by a healthcare professional without assistance from AI software

2.18 Non-enhanced CT brain scans may be reviewed by a radiologist, specialist radiologist, radiographer, stroke physician or emergency medicine physician, depending on availability of staff. CT angiography and CT perfusion brain scans are more likely to be reviewed by a radiologist, neuroradiologist or an interventional neuroradiologist, who specialise in interpretation of these scans.

3 Committee discussion

The diagnostics advisory committee looked at evidence for artificial intelligence (AI) software across 3 indications. These indications, and the technologies available for each one, are outlined below.

It considered evidence on the following technologies for guiding thrombolysis treatment decisions for people with suspected acute stroke using a non-enhanced CT scan:

- Accipio (MaxQ AI)
- Aidoc (Aidoc)
- Biomind (Biomind.ai)
- Brainscan CT (Brainscan.ai)
- CINA Head (Avicenna)
- e-Stroke (Brainomix)
- Neuro Solution (Nanox.AI)
- qER (Qure.ai)
- RapidAI (Ischemaview)
- Viz (Viz.ai).

It considered evidence on the following technologies for guiding mechanical thrombectomy decisions for people with an ischaemic stroke using CT angiography:

- Aidoc (Aidoc)
- CINA head (Avicenna)
- e-Stroke (Brainomix)
- RapidAI (Ischemaview)
- Viz (Viz.ai).

And evidence on the following technologies for guiding mechanical thrombectomy treatment decisions for people with ischaemic stroke using CT perfusion after a CT angiography brain scan:

- Cercare (Perfusion) (Cercare Medical)
- CT Perfusion 4D (GE Healthcare)
- e-Stroke (Brainomix)
- icobrain ct (icometrix)
- RapidAI (Ischemaview)
- Viz (Viz.ai).

Evidence was considered from several sources, including a diagnostics assessment report and an overview of that report. Full details are in the project documents for this guidance.

Quality of life is important to people who survive stroke

3.1 The patient expert explained that stroke adversely affects quality of life for many people who survive it. In addition to physical disability, long-term effects include fatigue, cognitive impairment, difficulty with language or speech (aphasia), poor mental health and emotional lability (exaggerated emotions that can be difficult to control). Around 50% of people who survive a stroke at a working age never return to work**.** Stroke often substantially affects also the lives of relatives and friends. The patient expert advised that it is important to understand the effect of AI-software technologies when used alongside clinician interpretation of CT brain images on clinical outcomes and the related quality of life after stroke. The committee recognised that quality of life is important to people who survive stroke.

The AI-software technologies do not automatically adapt and improve if the software is employed in the NHS

3.2 The committee discussed the nature of the algorithms in AI-software technologies and if the software could learn from the CT scan data in the setting it was used in. The manufacturers said that data from scans the software is used on in clinical practice is not used to further develop algorithms in the software. Instead, the algorithms in the software are developed using CT scans held by the company or accessed through research studies and regulatory approval for it sought before an updated static algorithm is released for use in clinical practice. The committee recognised that all AI-software technologies in clinical settings use fixed algorithms and cannot adapt and improve in real time using data from the clinical practice setting in which they are used.

Clinical effectiveness

No published evidence was found for many of the technologies in the assessment

3.3 The committee considered the available evidence for each technology and indication. It noted that the external assessment group's (EAG's) review found no published evidence for Accipio, Aidoc, Biomind, Brainscan CT, Cercare (Perfusion), CT Perfusion 4D, icobrain ct, Neuro Solution or qER for the indications in the assessment. The committee were therefore unable to consider these technologies further as part of its discussions and recommended more research on these technologies (see sections 4.2 to 4.4).

There is no evidence on the diagnostic accuracy of AI-software technologies when used in conjunction with clinician interpretation

3.4 The EAG's review found 15 diagnostic accuracy studies but these all evaluated the performance of the AI software as a standalone intervention and not alongside clinician interpretation (as it is intended to be used). Also, the risk of bias because of patient selection in many studies was high, particularly when they used a case-control study design, or unclear because of inadequate reporting. The reference standard used in the studies ranged from review by a single clinician to a panel of clinicians but it was often unclear whether these clinicians were blinded to the output from the AI software and difficult to determine if they were likely to correctly classify the target condition as their experience was not clearly reported. Therefore, because the studies were not generalisable to how the technologies would be used in practice, the conclusions that could be drawn on the accuracy of the technologies was limited. Further, the committee noted that none of the studies separately reported accuracy for people over the age of 80 with cerebrovascular disease when interpretation of scans is often more challenging. The committee concluded that the accuracy of the AI-software technologies is unclear and recommended that further research is done to estimate the diagnostic

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accuracy of the technologies when used alongside clinician interpretation in all 3 indications (see sections 4.2 to 4.4).

It was difficult to draw conclusions on the comparative accuracy data that was reported

3.5 The committee recognised that 1 study (Seker et al. 2020), relevant to guiding mechanical thrombectomy decisions for people with an ischaemic stroke using CT angiography, reported some comparative accuracy data. It reported data both on the accuracy of e-CTA software (Brainomix) alone and for scan reviews done by clinicians of varying experience alone compared with a common reference standard. This was an experienced neuroradiologist who had access to both imaging and clinical data. This is important because the usefulness of AI software-assisted scan review may vary between centres with differing levels of stroke specialism, and between different types of clinicians (for example, doctors in hospital emergency departments, stroke specialists, radiologists and neuroradiologists). But the committee noted that it is difficult to draw conclusions from the study on how the software would perform when used alongside clinician review because it did not provide information on whether clinicians and the software missed the same or different cases.

It is uncertain whether using AI-software technologies to help guide treatment decisions in stroke leads to faster access to treatment

3.6 In the EAG's review, there were 7 observational studies that compared time to treatment before and after implementing AI software in clinical practice. Most of the studies suggested that time to treatment for people who had thrombectomy or thrombolysis had reduced after implementing the software. The EAG reported that there was a high risk of bias in these studies because of the limited information they included. The studies were all retrospective, study populations and stroke care settings were not clearly described, the point in the care pathway when software was used and by whom was often unclear. Also, it was unclear if the before and after populations had similar characteristics, and whether adding the

software was the only change to the care pathway. Because only patients with a positive scan result were included in the studies, it is unclear whether patients with a false negative result would experience a delay in treatment. The committee concluded that it is uncertain whether using AI software to help guide treatment decisions in stroke leads to faster access to thrombolysis or thrombectomy. The committee recommended that further research is done to assess the effect of the AI-software technologies when used alongside clinician interpretation on time to treatment in all 3 indications (see sections 4.2 to 4.4).

It is unclear whether using AI software technologies to help guide treatment decisions in stroke leads to better clinical outcomes

3.7 The committee noted that the studies which compared time to treatment before and after implementing AI software provided limited information on how it affected clinical outcomes. In particular, there was no information on clinical outcomes when AI software was used for guiding thrombolysis treatment decisions for people with suspected acute stroke using a non-enhanced CT scan. Six studies, in which software was used for guiding mechanical thrombectomy using CT angiography or CT perfusion brain scans, reported on the proportion of people who were functionally more independent (with modified Rankin Scale [mRS] score 2 or less), length of hospital stay, mean 90-day mRS score and rate of complications and death during hospital stay after software implementation. The committee noted that the results from these studies were conflicting with some reporting a positive and others a negative impact. The EAG advised that the studies were unlikely to have been appropriately set up to adequately capture any differences in clinical outcomes. Therefore, the reported data are unlikely to show the true effects of implementing the technologies. The EAG further highlighted that the evidence described outcomes only for people who had a thrombectomy. Clinical experts explained that while using AI software could help improve outcomes for people who are offered treatment if it is received sooner, it could also worsen outcomes for people who were not offered treatment or who received incorrect

treatment if their diagnosis was missed because of the influence of the software on clinical decision making. The committee recognised that the potential benefits and risks of using AI software to help guide treatment decisions in stroke are not clear. The committee concluded that further research is needed to assess clinical outcomes in all 3 indications (see sections 4.2 to 4.4). It further concluded that to fully understand the benefits and risks of using AI software to help guide treatment decisions in stroke, data needs to be gathered from everyone having imaging, and not just from those who were subsequently offered treatment (see section 4.1).

More information about the reliability of AI-software technologies to help guide treatment decisions in stroke is needed

3.8 Only 1 published study (Kauw et al. 2020) reported on the technical failure rate of AI software. This study reported that the software failed to process CT perfusion brain scan data and return results to assist the review of 20 of the 176 scans (11%) included in the analysis. Causes for failures were severe motion, streak artifact and poor arrival of contrast. The clinical experts advised that it is possible that the failure in clinical practice may be even higher. The patient expert raised concerns that technical failures could result delays in diagnosis and access to time-sensitive treatments. The committee concluded that the reliability of AI software to help guide treatment decisions in stroke in clinical practice is not clear. It recommended further research to measure technical failure rates of AI software technologies used to help guide treatment decisions in stroke in all 3 indications (see sections 4.2 to 4.4). Information about the reasons for test failures should be recorded.

Cost effectiveness

There was not enough clinical evidence to evaluate the cost effectiveness of AI software in 2 of the 3 assessed indications

3.9 Evidence on using AI-software technologies for guiding thrombolysis treatment decisions for people with suspected acute stroke using a non-enhanced CT scan and mechanical thrombectomy treatment decisions for people with ischaemic stroke using CT perfusion after a CT angiography brain scan was very limited. In particular, there was no evidence on diagnostic accuracy of the technologies when used alongside clinician interpretation or how they might perform relative to clinician alone in either indication (see section 3.4). No clinical outcomes were reported for the use of AI software for guiding thrombolysis treatment decisions for people with suspected acute stroke (see section 3.7). So, the EAG did not build health economic models to evaluate the cost effectiveness of the AI software in these 2 indications. The committee concluded that it would be useful to understand the cost effectiveness of the AI software technologies in these indications but accepted that there is currently not enough data available to inform modelling.

Accuracy estimates in the model for using AI software in thrombectomy decisions may not reflect the accuracy seen in clinical practice

3.10 The EAG explained that because there was more data related to using AI software technologies for guiding mechanical thrombectomy decisions for people with an ischaemic stroke using CT angiography than for the other 2 indications (see section 3.4 and 3.6), it could build an exploratory economic model for this. Because no diagnostic accuracy data was available for using the technologies as intended (see section 3.4), the EAG elicited accuracy estimates for the model from clinical experts. These estimates were sought for a hypothetical average AI-software technology when used alongside clinician interpretation and also for the comparator in the model, clinician interpretation alone. The committee noted that it is challenging for people to estimate something like accuracy

that they cannot directly see. The committee concluded that while expert elicitation is an appropriate method to obtain model inputs when data is scarce, it is uncertain if the accuracy estimates in the model reflect the accuracy of the AI-software technologies that would be seen in clinical practice.

Health-related quality of life, given the exploratory nature of the model, is adequately captured

3.11 The committee considered whether the model captured the effect that having a stroke has on people's quality of life. The EAG explained that the utility values for health-related quality of life used in the base case were linked to the modified Rankin Scale (mRS) health states, from Rivero-Arias et al. (2010). This study used mRS and EQ-5D-3L information that was collected from people with stroke or transient ischaemic attack who took part in the Oxford Vascular Study (OXVASC) in the UK. The committee concluded that the health-related quality of life, given the exploratory nature of the model, was adequately captured but recalled how important quality of life is to people who survive stroke (see section 3.1). It considered that better understanding of health-related quality of life after stroke, in particular aspects such as emotional lability and fatigue that are important to people who survive stroke, would be helpful. It noted that the research priorities from the Stroke Priority Setting Partnership (led by the Stroke Association with the James Lind Alliance) and research needs from the National Stroke Programme (NHS Accelerated Access Collaborative) include understanding and managing emotional and psychological effects of stroke that may be less visible.

Cost effectiveness of AI-software technologies cannot be determined

3.12 The committee considered whether it was possible to determine the cost effectiveness of AI-software technologies for guiding mechanical thrombectomy decisions for people with an ischaemic stroke using CT angiography from the EAG's model. It recalled that the model was built using diagnostic accuracy estimates elicited from experts (see section

3.10). This meant that the model did not reflect any of the individual AI-software technologies but modelled a hypothetical average AI-software technology. The committee noted that in reality, the different technologies may perform differently from this modelled average technology but acknowledged that there was no evidence on their performance when used as intended (see section 3.4). The committee concluded that cost effectiveness of AI-software technologies for guiding mechanical thrombectomy decisions for people with an ischaemic stroke using CT angiography cannot be determined from the EAG's model. It recalled that no models were built to assess AI software technologies for the 2 other indications (see section 3.8). The committee concluded it would be useful to understand cost effectiveness in all 3 indications but that there is not enough data to support this at present. The committee recommended that further research is done to show clinical effectiveness in all 3 indications (see sections 4.2 to 4.4).

There is not enough data to recommend the AI-software technologies for routine use in the NHS

3.13 The committee considered that there is interest in the NHS around using AI-software technologies. It recognised the value of more accurate diagnosis and faster access to appropriate treatment that can lead to better outcomes and quality of life for patients, but acknowledged that there is currently not enough evidence to support using AI-software technologies to help guide treatment decisions in stroke. So, the full benefits and risks of their use cannot be reliably quantified, and their cost effectiveness cannot be adequately assessed. The committee concluded that it was unable to recommend the routine use of the AI-software technologies to help guide treatment decisions in stroke. It recommended further research on the technologies in all 3 indications (see sections 4.1 to 4.5).

4 Recommendations for further research

4.1 The committee recommended more research on the AI-software technologies in all 3 indications, specifically comparing diagnostic accuracy and outcomes of an AI technology plus a clinician looking at the scans, compared with clinician alone. Ideally, studies would be prospective, they should be done in comprehensive and acute stroke centres, describe the level of experience of the clinicians interpreting the CT brain scans and include both people who had and did not have a particular type of treatment. Studies should also consider reporting data separately in subgroups when using the technologies may be particularly useful or less effective (for example in older people, particularly those over the age of 80, with small vessel disease and calcification of the cerebrovasculature). The specific research recommendations for each indication are detailed in sections 4.2 to 4.4.

4.2 For guiding thrombolysis treatment decisions for people with suspected acute stroke using a non-enhanced CT scan research is recommended on:

- the accuracy of Accipio, Aidoc, Biomind, Brainscan CT, CINA head, e-Stroke, Neuro Solution, qER, RapidAI or Viz plus clinician compared with clinician alone, in identifying stroke and determining whether it is ischaemic or haemorrhagic
- test failure rate with causes of failures
- time to thrombolysis
- short-term clinical outcomes with the National Institutes of Health Stroke Scale (NIHSS) at 24 hours after treatment and modified Rankin Scale (mRS) at 90 days.

4.3 For CT angiography brain scans for guiding mechanical thrombectomy treatment decisions for people with ischaemic stroke using CT angiography, research is recommended on:

- the accuracy of Aidoc, CINA head, e-Stroke, RapidAI or Viz plus clinician compared with clinician alone, in determining whether or not thrombectomy is appropriate
- test failure rate with causes of failures
- time to thrombectomy
- short-term clinical outcomes with the National Institutes of Health Stroke Scale (NIHSS) at 24 hours after treatment and modified Rankin Scale (mRS) at 90 days.

4.4 For guiding mechanical thrombectomy treatment decisions for people with ischaemic stroke using CT perfusion after a CT angiography brain scan, research is recommended on:

- the accuracy of Cercare (Perfusion), CT Perfusion 4D, e-Stroke, icobrain ct, RapidAI or Viz plus clinician compared with clinician alone, in determining whether or not thrombectomy is appropriate
- test failure rate with causes of failures
- time to thrombectomy
- short-term clinical outcomes with the National Institutes of Health Stroke Scale (NIHSS) at 24 hours after treatment and modified Rankin Scale (mRS) at 90 days.

5 Implementation

NICE intends to develop tools, in association with relevant stakeholders, to help organisations put this guidance into practice.

In addition, NICE will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be considered by the NICE Medical Technologies Evaluation Programme research facilitation team for developing specific research study protocols as appropriate. NICE will also incorporate the research recommendations in section 4 into its guidance research recommendations database and highlight these recommendations to public research bodies.

6 Review

NICE reviews the evidence 3 years after publication to ensure that any relevant new evidence is identified. However, NICE may review and update the guidance at any time if significant new evidence becomes available.

Mark Kroese

Chair, diagnostics advisory committee

March 2022

7 Diagnostics advisory committee members and NICE project team

Committee members

This topic was considered by the diagnostics advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the test to be assessed. If it is considered there is a conflict of interest, the member is excluded from participating further in that assessment.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Additional specialist committee members took part in the discussions for this topic:

Specialist committee members

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NICE project team

Each diagnostics assessment is assigned to a team consisting of a technical analyst (who acts as the topic lead), a technical adviser and a project manager.

Tosin Oladapo and Suvi Härmälä

Topic leads

Rebecca Albrow, Thomas Walker and Amy Crossley

Technical advisers

Donna Barnes

Project manager

ISBN: