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Diagnostics Assessment Programme

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

The following document is made available to stakeholders:

1. Stakeholder comments on the Diagnostics Consultation Document (DCD) and responses

NICE National Institute for Health and Care Excellence

DIAGNOSTICS ASSESSMENT PROGRAMME

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

Diagnostics Consultation Document – Comments

Diagnostic Advisory Committee date: 22 August 2023

Comment number	Organisation	Section number	Comment	NICE Response
1	British Society of Neuroradiology	1	The BSNR Standards subcommittee are generally supportive of this guideline. 1. It recognises the investigational nature of these tools and their role as descision support rather than stand-alone software. 2. The high cost effectiveness of MT means that this software will be cost effective even if it only results in small increases in MT numbers/efficiency 3. The guideline recognises that the reason for the additional benefit is unknown and may relate to factors such as speed of image access rather than image processing. Our primary concern is that the evidence is insufficient to separate e-Stroke and RapidAI (+/- Viz.AI) in terms of NHS approval for use.	Thank you for this comment which the committee has considered. Responses to the concern raised can be found in the NICE responses to comments 2 and 3.
2	British Society of Neuroradiology	1.1	Can be used in the NHS with evidence generation The evidence used to separate these two platforms from the others is weak, with significant biases around patent selection, comparative outcomes, case-controls etc. The rapid access to imaging data is common to all of these platforms and is likely the major factor in accelerating care, and it appears unreasonable to exclude these other platforms from use on that basis.	Thank you for this comment which the committee has considered. In producing the recommendations, the NICE diagnostic advisory committee considered the data available for all technologies assessed. It noted that the external assessment group's (EAG's) review found no published evidence that met review inclusion criteria for 9 of the assessed technologies, and only 1 study was identified that assessed the CINA head

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			Section 3.18 also suggests Viz.Ai is included but it is not here. We do not regard the evidence as sufficient to make the distinction between 'use' and 'don't use' in the NHS clinical context. By making this recommendation most other platforms will be unable to be used in clinical contexts unless separate dedicated funding can be identified.	software, and this only reported accuracy data for the technology used as a standalone intervention and not alongside clinician interpretation (as it is intended to be used; see section 3.6 of the guidance document). More data were identified for 3 technologies (e-Stroke, RapidAI and Viz) including impact on time to treatment and how many people get treatment. Because of this the committee concluded that these technologies could be used in the NHS while further evidence is generated. But for the remaining technologies with less supporting data, use should only be used in research (see section 3.19 of the guidance document). For Viz.ai, we are working with the company to understand the regulatory status of this technology.
3	British Society of Neuroradiology	1.3	Can only be used in research All of the technologies offer rapid image sharing and communication tools which are probably one of the major benefits. On this basis it appears isunreasonable to effectively exclude the majority from NHS clinical use. Until and unless more robust evidence is available our view is that all tools should be regarded as investigational decision support tools, and linked to robust audit or research data when used to develop appropriate evidence.	Thank you for this comment which the committee has considered. As described in the response to comment 2, the NICE diagnostic advisory committee considered that there was sufficient differences in the data available to make different recommendations for the assessed technologies. The recommendations state that further data should be generated, for some technologies while they are used in the NHS (see section 1.1 of the guidance document) and for other through use only in research (see section 1.3 of the guidance document).
4	British Society of Neuroradiology	1.5	Evidence generation and further research Fully agree, evidence is lacking but the software is already live in most/all centres performing thrombectomy, for reasons of speed of access and possibly decision support particularly in 'spoke' centres referring for MT.	Thank you for this comment which the committee has considered. The committee noted the current use of the technologies in the NHS and the implications for further data generation (described in section 3.20 of the guidance).

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5	British Society of Neuroradiology	2.4	Clinical need and practice Irregularities is an unusual term to use - imaging abnormalities/findings may be better?	Thank you for this comment which the committee has considered. Section 2.4 of the guidance has now been reworded to state 'imaging abnormalities or findings' instead of 'irregularities.
6	British Society of Neuroradiology	2.4	Clinical need and practice Agree that the rapid communication of imaging findings is a large part of the benefit.	Thank you for this comment which the committee considered.
7	British Society of Neuroradiology	2.17	The interventions Recently published evidence supports Viz.AI reducing the time to thrombectomy Martinez-Gutierrez JC, Kim Y, Salazar-Marioni S, et al. Automated Large Vessel Occlusion Detection Software and Thrombectomy Treatment Times: A Cluster Randomized Clinical Trial. JAMA Neurol. Published online September 18, 2023. doi:10.1001/jamaneurol.2023.3206	Thank you for this comment which the committee has considered. The abstract of this study was highlighted in consultation comments received on the EAG's updated report and was considered by committee at the meeting on 22 August 2023. This included data on the impact of Viz.ai on time to thrombectomy.
8	British Society of Neuroradiology	2.18	The comparator This should also reference the lack of a rapid image transfer tool in addition.	Thank you for this comment which the committee has considered. Section 2.18 of the guidance has been updated to specify that the comparator comprises image sharing function. We have further explained this within section 2.18 of the guidance by stating 'Image sharing between sites is based on current NHS practice (without use of the technologies being assessed as part of this guidance)'.

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9	The Society and College of Radiographers	General	Reassuring to have NICE evaluation of AI technologies. Content of this document is well balanced	Thank you for this comment which the committee considered.
10	The Society and College of Radiographers	1.1	Can be used in the NHS with evidence generation 'scans for people who have had a stroke' or clinical suspicion that the person has had a stroke - this might not be confirmed prior to stroke?	Thank you for this comment which the committee has considered. Section 1.1 of the guidance now specifies that the technologies can be used for people who have had a 'suspected' stroke.
11	The Society and College of Radiographers	1.5	Evidence generation and further research 'test failure rate' - is it test failure rate or rather AI software failure rate?	Thank you for this comment which the committee has considered. Section 1.5 of the guidance has been amended to clarify that further evidence is needed on how often software is unable to analyse CT scans, with reasons for this. This also reflects the changes in wording in section 3.12 of the guidance (see the response to comment 14 below).
12	The Society and College of Radiographers	2.18	The comparator Please add the word 'diagnostic' to precede radiographer. Health and Care Professions Council regulates diagnostic radiographer and therapeutic radiographer titles. Therapeutic radiographers do not review non-enhanced CT brain scans for stroke.	Thank you for this comment which the committee has considered. This has been amended in section 2.18 of the guidance and the word 'diagnostic' has been added to precede radiographer title.
13	The Society and College of Radiographers	3.4	The image sharing function of the technologies could be a key driver of potential benefit With respect to substantial cost to upgrade existing systems. The cost of rapid image transfer associated with the AI-derived software is not known for the majority of companies (outlined in section 2). Therefore it is not possible to comment whether this is a cost saving to the	Thank you for this comment which the committee has considered. Costs are known for 6 technologies (Aidoc, CINA head, e-Stroke, icobrain ct, RapidAI, and Viz; see section 2 of the guidance), including those recommended for use in the NHS while more evidence is generated. These values were used

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			NHS as opposed to upgrade of the system. It is important to note that an upgrade to the system would facilitate rapid transfer of images associated with the multiple modalities, specialties and body parts which radiology services image each day (approximately 40 million examinations per year in England) beyond CT stroke imaging.	to inform cost effectiveness modelling done to support the guidance.
14	The Society and College of Radiographers	3.12	More information about the reliability of AI-derived software to help guide treatment decisions in stroke is needed The technical failures listed here are not technical failures of the AI-derived software. Technical failure associated with motion and streak artefact, also presence of contrast agent are related to patient condition, anatomy, or CT scan acquisition errors not specific to AI-derived software errors.	Thank you for this comment which the committee has considered. The failure rate referred to in section 3.12 of the guidance is described as post-processing failure in the study cited in that section (Kauw et al. [2010]). This section has been updated to reflect this. In section 1.5 and 3.12 of the guidance we have amended the text to replace 'test failure rate' with 'how often software is unable to analyse CT data, with reasons for this' to clarify what the committee would like further evidence on.
15	The Society and College of Radiographers	3.16	Small increases in the number of thrombectomies done in the EAG's model are enough for the test to be cost effective. 'does not need to be large for it to be cost effective.' Specifically, how large would it need to be do be effective? Can the authors quantify 'not need to be large' ?	Thank you for this comment which the committee has considered. Given uncertainty in the model, particularly the number of false positive results that might be generated by the tests, it is not possible to give an exact figure. But exploratory analysis done by the NICE technical team suggested that this may be around an 0.25 percentage point increase in thrombectomies done.
16	The Society and College of Radiographers	3.16	Small increases in the number of thrombectomies done in the EAG's model are enough for the test to be cost effective	Thank you for this comment which the committee has considered.

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			'routinely show benefits from increased thrombectomy use' Are there also risks associated with increased thrombectomy use - if so, are those risks potentially more applicable to specific groups or populations?	The comment cited from the guidance related to a concern raised about uncertainty of the effectiveness of thrombectomy for additional people who would get the procedure if the software was adopted (potential risk that this wouldn't be effective for this group). But experts considered that this group would benefit (as described in section 3.16). The assessment didn't look at whether there are particular groups who may benefit more from, or have greater risk from, thrombectomy. The EAG's model included additional cost impact for false positive results (for ambulance transfer and time on a stroke unit) but assumed that people the software incorrectly identified as eligible for thrombectomy would be detected before the procedure occurred. Experts agreed that such cases would be detected before having an unnecessary thrombectomy (see section 3.17 in the guidance).
17	The Society and College of Radiographers	3.18	Cost effectiveness of AI-derived software is uncertain, but it is plausible they are cost effective 'small increases' Can the authors quantify what is meant by 'small increases'.	Thank you for this comment which the committee has considered. Please see the response to comment 15.
18	The Society and College of Radiographers	5	Given the rapid evolutions of AI-derived software in recent years and with AHSN reports due in year 3 of evaluation (next year) will it be possible to review at an earlier timeframe than 3 years?	Thank you for this comment which the committee has considered. NICE may review and update the guidance at any time if significant new evidence becomes available, so review could be earlier than 3 years.

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19	The British and Irish Association of Stroke Physicians	General	Dear NICE committee, Thank you for your response to our comments. We are pleased with the final recommendations and are grateful for your responsive and collegiate approach to the rapidly changing field of hyperacute stroke care. On behalf of the British and Irish Association of Stroke Physicians. [redacted]Consultant Stroke Physician Stroke and Elderly Medicine [redacted]	Thank you for this comment which the committee considered.