

Software with artificial intelligence derived algorithms for analysing CT brain scans in people with a suspected acute stroke

Diagnostics Assessment Report (DAR) - Comments

Stakeholder	Comment no.	Page no.	Section no.	Comment	EAG Response
The Society and College of Radiographers	1.	25	2.2	<i>For patients with suspected stroke, software using AI-derived algorithms may be a useful tool in the early stages of the treatment pathway, particularly where neuroradiologist assessment of the CT images is not directly available – please note there are reporting radiographers providing valuable assessment of CT images in the UK. This is a resource which may still be underutilised as the Society of Radiographers (SoR) notes repeated failure to acknowledge the impact radiographer reports have on the early detection of stroke.</i>	Comment only – no response required
The Society and College of Radiographers	2.	26	2.2	The SoR acknowledges the RCR guidance on integrating artificial intelligence with the radiology reporting workflows and would suggest in addition to standard 1. that AI must be integrated in reporting workflows seamlessly in a way that does not introduce delay to the issuing of a report as well as not adding extra burden to radiologists. Radiographers who report CT Brain scans in acute stroke are often doing so immediately when the images are acquired and sent to PACS. The introduction of AI should assist and not impede the rapid turnaround of these actionable reports.	Comment on implementation – no response required
The Society and College of Radiographers	3.	30	Fig 1	If, as this illustration suggests, Icometrix and Aidoc comprehensive stroke solution pathway requires patients to go on and have perfusion analysis and LVO detection on CT with contrast each time it detects images which are negative for ICH, this could add a large and potentially unnecessary radiation burden to patients. If no ICH is detected, a human reporter (radiologist or radiographer) may often detect signs of early acute stroke and make a different decision regarding further imaging, for example, cerebral angiogram or MRI and not perfusion scanning, which is recommended only if more than 6 hours have elapsed from symptom onset. NICE guideline [NG128]	AI technologies, in this assessment have been evaluated as an adjunct to human interpretation (as specified in the scope and as indicated by this comment)
The Society and College of Radiographers	4.	37	2.4.3	The SoR welcomes the recognition here of <i>appropriately trained staff and professionals trained to interpret images. Alteplase should be administered in a well organised stroke service with appropriately trained staff to deliver thrombolysis and</i>	Comment only – no response required

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				<i>monitor for any complications, nurse staff trained in acute stroke care and immediate access to brain imaging with professionals trained to interpret images</i>	
The Society and College of Radiographers	5.	139	6	SoR supports the conclusion of this study that the available evidence is not suitable to determine the clinical effectiveness of using AI-derived software to support the review of CT brain scans in acute stroke, in the NHS setting.	Comment only – no response required
The Society and College of Radiographers	6.	139	6.2	SoR supports the suggested research priority, future studies should compare the performance of the AI-derived software technology in combination with a human reader to that of the human reader alone, where interpretation by an experienced expert or panel of experts provides the reference standard.	Comment only – no response required
The Society and College of Radiographers	7.	139	6.2	SoR advocate that beyond evaluating technologies as they would be implemented in practice, it is essential and pragmatic for innovators and developers to initially consult with staff and patients at development stage, to determine where there is high clinical need for service re-design and / or innovation.	Comment only – no response required
Brainomix	8.	17/18	Scientific summary	<p>We would welcome the explicit acknowledgement that the studies listed are not directly comparable. As alluded to the case mix of the studies will determine the performance of the studies and in particular the prevalence of distal versus proximal occlusion in the population. A similar comment can be made for ICH, i.e. the case mix will dictate the performance.</p> <p>Why is the summary of LVO detection performance highlighted in the summary, but not the ICH performances?</p>	<p>This issue has been comprehensively discussed in the body of the report and the report does not attempt (either in the scientific summary or the body of the report) to draw direct comparisons between AI technologies.</p> <p>The content of the scientific summary is constrained by the word limit specified for this section of the report.</p>
Brainomix	9.	21	1	Typographic error – first bullet should be labelled “1”	Thank you for noting this error, we will correct it ahead of publication
Brainomix	10.	31	2.2.5	e-ASPECTS also identifies and segments hyperdensity likely to be ICH and hyperdensities likely to reflect hyperdense middle cerebral arteries reflective of thrombosis	This is background information, which does not affect the findings of the assessment, we will consider adding text to the background section ahead of publication

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Brainomix	11.	32	2.2.5	e-Stroke outputs can also be viewed through a smartphone app in addition to the other platforms	This is background information, which does not affect the findings of the assessment, we will consider adding text to the background section ahead of publication
Brainomix	12.	132	5.2.1	We were interested by the discussion of studies outside of the remit of the paper related to the value of e-Stroke biomarkers on patient outcome, but, as acknowledged, this is not strictly related to the evaluation question. There is good evidence of with or without AI for this type of decision making, which might be more relevant to this discussion (e-ASPECTS software improves interobserver agreement and accuracy of interpretation of aspects score - PubMed (nih.gov)).	This aspect of the discussion was included as being an area which may be considered of potential interest for future research. We thank the stakeholder for noting a further publication of interest, but note that the discussion was not intended to be a comprehensive review of all publications in this area.
Brainomix	13.	62	Table 7	Herweh 2020 (abstract) can be replaced by the peer reviewed publication throughout the document (Automated detection and segmentation of intracranial hemorrhage suspect hyperdensities in non-contrast-enhanced CT scans of acute stroke patients SpringerLink)	It would not be appropriate to replace the Herweh 2020 (abstract) with the full publication, as the information in the report was based on the abstract only (i.e. the abstract is the correct citation for this content). The full paper was published after the date of the final up-date searches for this assessment; up-date searches were conducted in October 2021 and the full paper was published in November 2021.
Brainomix	14.	62	Table 8	Effectiveness data from another centre (in the UK NHS) are available here: page 28, abstract 111. WSO Congress supplement (sagepub.com) .	This abstract was not identified by our searches, as it was published in WSO congress supplement which was first made available 27/10/21; this was after the date of the last conference searches on Conference Proceedings Citation Index (Web of Science) and Northern Light Life Sciences (July 2021) and the date of the Embase update search for the main search strategy (18 th October 2021). The reported time outcome ('door in to door out' rather than time to intervention/catheter insertion) is outside the scope of this assessment. The committee may wish to note that this abstract does report that: A) a similar proportion of patients, referred for thrombectomy, were transferred before the

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					<p>implantation of e-Stroke (19/22 [86.4%])⁰ and after implantation (21/25 [84%])</p> <p>B) a higher proportion of patients, who received thrombectomy, achieved functional independence (mRS 0-2) at 3 month following implementation of e-Stroke (48%) vs. before implementation (16%)</p> <p>As with other studies of this type, which were included in the report, this study has the following key limitations:</p> <ul style="list-style-type: none"> • Insufficient information was provided to determine how e-stroke had been implemented and whether there were any other changes to the care pathway or patient mix that may have affected clinical outcomes • The information provided is limited to those patients who underwent thrombectomy, i.e., there is no information about the performance of e-Stroke, on the identification of patients who are candidates for thrombectomy • The sample size was very small
Brainomix	15.	NA - general		<p>ASPECTS is widely used by doctors to triage patients for MT, both within the UK (e.g. Signpost Mechanical Thrombectomy The Royal London Hospital, Thames-Valley-Thrombectomy-Referral-Pathway_V1.1_2021.pdf (oxfordahsn.org)) and without (e.g. European Stroke Organisation (ESO) - European Society for Minimally Invasive Neurological Therapy (ESMINT) Guidelines on Mechanical Thrombectomy in Acute Ischemic Stroke Journal of NeuroInterventional Surgery (bmj.com)).</p> <p>It seems a missed opportunity for the most common imaging selection criterion used in UK practice for patient selection for MT</p>	<p>This assessment followed the agreed scope, which as discussed in our report, did not include triage.</p> <p>The evaluation of this potential application of AI may be a consideration for future assessments.</p>

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				is not included in the review. We would suggest inclusion of this subtopic.	
Icometrix	16.	28	2.2.1	In the meantime, there was a version 6 was released.	Point of information, which may be relevant for future up-dates

Section B: Comments on the economic model (please add further rows as required)

	Issue	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)
The Society and College of Radiographers		Nothing further to comment thanks.		No response required