NICE National Institute for Health and Care Excellence

Diagnostics Assessment Programme
AI software to help clinical decision making in stroke
NHS organisation submission

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

The NHS provides a unique perspective on the technology, which is not typically available from the published literature. NICE believes it is important to involve NHS organisations that are responsible for commissioning and delivering care in the NHS in the process of making decisions about how technologies should be used in the NHS.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Short, focused answers, giving the NHS perspective on the issues you think the committee needs to consider, are what we need.

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About you

Your name	[redacted]
Name of your organisation	NHS England GIRFT Programme
Please indicate your position in the organisation	NHS, Department of Health and Social Care or Welsh Government in general? • Commissioning services for the Department of Health and Social Care or Welsh Government specific to the condition for which NICE is considering this technology? • Responsible for quality of service delivery in the ICS (e.g. medical director, public health director, director of nursing)? • A specialist in the treatment of people with the condition for which NICE is considering this technology? • A specialist in the clinical evidence base that is to support the technology (e.g. participation in clinical trials for the technology)? • Other (please specify): Consultant Stroke Physician, East Kent Hospitals University Foundation Trust (EKHUFT). Clinical lead for Stroke: EKHUFT & South East (Wessex, BOB, Kent, Surrey and Sussex) NHS England. National Speciality Adviser for Stroke Medicine – NHS England. National Clinical Lead for Stroke Medicine - NHS England GIRFT Programme.
Do you have any links with, or funding from, the tobacco industry? Please declare any direct or indirect links to, and receipt of funding from the tobacco industry	No

Equality

Please let us know if you think that this evaluation: **Could exclude from full consideration any people protected by the equality legislation who fall within the patient population.** **Could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology** **Could lead to recommendations that have any adverse impact on people with a particular disability or disabilities.**	
Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.	

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

Please include here any issues you would like the committee to consider when evaluating this technology	***Scope*** • AI is used to support CT, CTA +/- CTP together so trying to deconstruct impact on care per module is artificial, of limited value and difficult to see how such a study would be designed and then be representative. • AI is a decision support software. It can improve accuracy and speed of decision making but is part of a complex system of care to improve patient outcomes. The opportunity to add value includes improved or accelerated patient identification, improved stratification / patient selection, improved image viewing access and communication, justification for CTA/CTP acquisition (in the absence of a real time radiology input AI is better than the standard). In the same way that access to CT angiography might be required to deliver MT services, support with real time image interpretation can support high quality of care delivery, but neither is sufficient. If you lack an MT service / don't use the results / don't have a good rehab MDT the value is much diminished / extinguished… • The primary outcome should reflect that these tools are diagnostic decision support tools and their impact on patient flow through rapid image transfer as well as diagnostic interpretation, i.e. it should not be purely about accuracy. Impact on patient outcome has to be modelled in this setting and will be dependent on the system in which it is implemented, i.e. lower performing systems may benefit more but only if the dependent components of a good pathway are in place. The study suggests 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 focus on the software as a diagnostic has possibly rendered other findings inconsequential whereas in terms of delivering an optimal pathway with rapid diagnosis further investigation would be warranted. The review failed to take on board the rapid image transfer functionality of these products so that the CSC stroke physician and/or INR can look at the scans immediately. It is not the diagnostic accuracy that is the MOST VALUABLE feature of the AI products and speaks to the point made by the independent DAR abstract. We don't need more evidence to know this is a benefit. The NHS imaging system isn't going to change to be able to do this in place of these products. For say 100 referrals it took as a minimum 20 min longer to sit at a screen and wait for the NHS PACS images to come through. So counting just the time of the CSC stroke physician £200 / hour with all on costs/overheads that's about 250 per LVO we look at to get to the 100 so it's a saving of £16,000K pa for a centre taking 100 MT transfers and that's not counting any clinical benefits from more rapid decision making. • There appears to be a failure to acknowledge that under no scenario in the NHS will an INR look at every CTA in acute stroke patients to provide an expert read on whether they have an LVO (and this is not necessary). If the panel is suggesting it is not as good as the experts and not recommending it for the NHS; it is suggesting the NHS needs to get every scan looked at by an INR – this is just not practical nor necessary? • The types of evidence that might reasonably inform this evaluation are not limited to traditional systematic reviews. With hundreds of thousands of patients processed there is clearly data out there to answer a raft of questions. At the very least there is unlikely to be significant

harm and there is significant evidence suggesting the AI support is adding value. You would only need to enable one more MT to easily pay for >1 year licence from a health economic perspective.

- NCCT solutions can often include blood detection, but this is not designed to make IVT decisions better – users should be competent at this. It is included in the software packages to make the ischaemia quantification more sensible an output.

- No provider claims to offer a diagnostic for ischaemic stroke using NCCT, rather the software output should be considered when a clinical diagnosis has been made. Such use would be outside the intended use of any of the softwares, so it is not clear why it is the "diagnosis" of ICH or AIS from an isolated NCCT that was tested…?

- Given ASPECTS is the most common criterion used on NCCT for consideration of MT it is not clear why this was not included as it is an area where software stands to offer most.

- How can software to support CTP analysis not be the standard of care? It is impossible to use CTP in the Late Time Window (LTW) without software for the majority of users and the only evidence for LTW patient treatment for both MT and IV rpta used software. It is not clear that LTW patient selection without using software could ever be ethical in a research setting.

- Section 2.4 states that *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* – this neatly encompasses how the introduction of this digital element has connected the right information with the right people, leading to the right decisions being made for the right patients. I.e. it is part of a system of care provision which adds value, saves time and improves outcomes

- Re section 3.3. - The products for which there is no published evidence are currently not used by any stroke services in England, a position which is not expected to change any time soon.

Evidence considered

- Only publications in peer reviewed journals were considered, other than a single unpublished study from a committee member ([*62] Mair G, White P, Bath PM, Muir KW, Al-Shahi Salman R, Martin C, et al. External validation of Artificial Intelligence software to interpret brain CT in patients with acute stroke: the Real-world Independent Testing of e-ASPECTS Software Study (RITeS). 2021 [PrePrint provided by the author]) – which I note is now published but wasn't at the time of the review –Why unpublished evidence from a committee member was allowed but not unpublished evidence from AI providers seems entirely inappropriate from a process perspective.

- There is evidence of impact on accuracy when adding decision support (see page 5: "There is no evidence on their diagnostic accuracy when used alongside clinician interpretation."). This absolute statement is clearly not correct. Some of the evidence to support its use was included in the reference list but appears to have been ignored (*Brinjikji W, Abbasi M, Arnold C, Benson JC, Braksick SA, Campeau N, et al. e-ASPECTS software improves interobserver agreement and accuracy of interpretation of aspects score. Interv Neuroradiol 2021:15910199211011861* and *Grunwald IQ, Kulikovski J, Reith W, Gerry S, Namias R, Politi M, et al. Collateral automation for triage in stroke: Evaluating automated scoring of collaterals in acute stroke on computed tomography scans. Cerebrovasc Dis 2019;47(5-6):217-22.*)

- In the independent DAR abstract 'However, results indicated that if the addition of AI-derived software assisted review for guiding mechanical thrombectomy treatment decisions increased the sensitivity of the diagnostic pathway (i.e., reduced the proportion of undetected LVO's), this may be considered cost-effective.' There is little doubt that real world experience of both referring sites and CSC MT sites is that these products to that and also accelerate transfer of appropriate patients for MT shortening DIDO times.

- Given there are hundreds of hospitals who continue to use and pay for the software, It would seem odd to say there is no evidence of value in this setting...? Perhaps the evidence can be found outside of peer-reviewed publications by asking people why they use it? - *some great evidence coming out of Barts, Oxford and Royal Berkshire, Brighton etc to support its use*

- Evidence that would also be relevant that was not included:
  https://pubmed.ncbi.nlm.nih.gov/35134802/ - real world impact observed when e-Stroke implemented
  https://pubmed.ncbi.nlm.nih.gov/33527886/ - accuracy of e-CTA to notify LVO
  https://pubmed.ncbi.nlm.nih.gov/33853441/ - ability of e-ASPECTS to improve readers doing ASPECTS scores

Unanswered questions, need for further data:

- [redacted] The false negative risk is really not relevant – it assumes that the products are being used instead of a radiology report – they aren't. If the product isn't there it isn't going to change when and who looks at and reports the scan. So worst case scenario, AI and the clinician looking at the CTA misses an LVO (which an INR would agree needs treatment) and it is picked up by usual reporting. The product itself doesn't introduce any more harm than is there already.

- The effect on clinical outcomes will only be shown through modelling the impact of earlier onset to treatment times through reducing DIDO times for patients with LVO. It will not be possible to do a trial or show impacts over time on clinical outcomes (90 day mRS) when so many other things in the system change e.g. referral criteria and expansion of service availability, changes in ambulance response times.

- It would be useful to do research/service evaluations understanding how clinicians use the software (Oxford AHSN are doing that).

Do clinicians (NHS or other) improve their performance when using software?

  - AI providers already have evidence from getting clinicians to look at set of scans with and without AI readout two weeks apart in randomised order showing reader performance is improved.

Suggestions:

- Make this an Early Value Assessment product. Licensed with a review following collection of further data.

I would also bring to your attention the recently published updated national guidance on stroke care which since I last wrote has additional references of the use of AI in stroke care since August 2022 National Clinical Guideline for Stroke (strokeguideline.org) which I note now considers eligibility for MT to have AI decision support as a standard requirement demonstrating efficacy and its use.

These are the main references considered as pertinent to the revised RCP 2023 guidelines:

G. W. Albers et al (2021). Assessment of Optimal Patient Selection for Endovascular Thrombectomy beyond 6 Hours after Symptom Onset: A Pooled Analysis of the AURORA Database. JAMA Neurology. 78: 9. 1064-1071.
G. W. Albers et al (2021). Assessment of Optimal Patient Selection for Endovascular Thrombectomy beyond 6 Hours after Symptom Onset: A Pooled Analysis of the AURORA Database. JAMA Neurology. 78: 9. 1064-1071.
G. W. Albers et al (2018). Thrombectomy for stroke at 6 to 16 hours with selection by perfusion imaging. New England Journal of Medicine. 378: 8.

	708-718.
	G. W. Albers et al (2018). Thrombectomy for stroke at 6 to 16 hours with selection by perfusion imaging. New England Journal of Medicine. 378: 8. 708-718.
	P. Bhuva et al (2020). Noncontrast Computed Tomography Alberta Stroke Program Early CT Score May Modify Intra-Arterial Treatment Effect in DAWN. Stroke. 2404-2412.
	P. Bhuva et al (2020). Noncontrast Computed Tomography Alberta Stroke Program Early CT Score May Modify Intra-Arterial Treatment Effect in DAWN. Stroke. 2404-2412.
	J. M. Boulanger et al (2018). Canadian Stroke Best Practice Recommendations for Acute Stroke Management: Prehospital, Emergency Department, and Acute Inpatient Stroke Care, 6th Edition, Update 2018. International Journal of Stroke. 13: 9. 949-984
	J. M. Boulanger et al (2018). Canadian Stroke Best Practice Recommendations for Acute Stroke Management: Prehospital, Emergency Department, and Acute Inpatient Stroke Care, 6th Edition, Update 2018. International Journal of Stroke. 13: 9. 949-984
	M. Bouslama et al (2021). Novel selection paradigms for endovascular stroke treatment in the extended time window. Journal of Neurology, Neurosurgery and Psychiatry. 92: 11. 1152-1157.
	M. Bouslama et al (2021). Novel selection paradigms for endovascular stroke treatment in the extended time window. Journal of Neurology, Neurosurgery and Psychiatry. 92: 11. 1152-1157.
	I. Casetta et al (2020). Endovascular Thrombectomy for Acute Ischemic Stroke beyond 6 Hours from Onset: A Real-World Experience. Stroke. 2051-2057.
	I. Casetta et al (2020). Endovascular Thrombectomy for Acute Ischemic Stroke beyond 6 Hours from Onset: A Real-World Experience. Stroke.

	2051-2057.
	L. Dekker et al (2021). Endovascular treatment in anterior circulation stroke beyond 6.5 hours after onset or time last seen well: Results from the MR CLEAN Registry. Stroke and Vascular Neurology. 6: 4. 572-580
	L. Dekker et al (2021). Endovascular treatment in anterior circulation stroke beyond 6.5 hours after onset or time last seen well: Results from the MR CLEAN Registry. Stroke and Vascular Neurology. 6: 4. 572-580
	P. S. Dhillon et al (2022). Association between time to treatment and clinical outcomes in endovascular thrombectomy beyond 6 hours without advanced imaging selection. Journal of NeuroInterventional Surgery. 18564
	P. S. Dhillon et al (2022). Association between time to treatment and clinical outcomes in endovascular thrombectomy beyond 6 hours without advanced imaging selection. Journal of NeuroInterventional Surgery. 18564
	P. S. Dhillon et al (2022). Perfusion Imaging for Endovascular Thrombectomy in Acute Ischemic Stroke Is Associated With Improved Functional Outcomes in the Early and Late Time Windows. Stroke.
	P. S. Dhillon et al (2022). Perfusion Imaging for Endovascular Thrombectomy in Acute Ischemic Stroke Is Associated With Improved Functional Outcomes in the Early and Late Time Windows. Stroke.
	M. Goyal et al (2015). Randomized Assessment of Rapid Endovascular Treatment of Ischemic Stroke New England Journal of Medicine. 372: 11. 1019-1030.
	M. Goyal et al (2015). Randomized Assessment of Rapid Endovascular Treatment of Ischemic Stroke New England Journal of Medicine. 372: 11. 1019-1030.
	A. P. Jadhav et al (2019). Benefit of Endovascular Thrombectomy by Mode of Onset: Secondary Analysis of the DAWN Trial. Stroke. 50: 11. 3141-3146.

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	A. P. Jadhav et al (2018). Eligibility for endovascular trial enrollment in the 6-to 24-hour time window analysis of a single comprehensive stroke center. Stroke. 49: 4. 1015-1017.
	A. P. Jadhav et al (2018). Eligibility for endovascular trial enrollment in the 6-to 24-hour time window analysis of a single comprehensive stroke center. Stroke. 49: 4. 1015-1017.
	T. G. Jovin et al (2022). Thrombectomy for anterior circulation stroke beyond 6 h from time last known well (AURORA): a systematic review and individual patient data meta-analysis. The Lancet. 399. 249-258.
	T. G. Jovin et al (2022). Thrombectomy for anterior circulation stroke beyond 6 h from time last known well (AURORA): a systematic review and individual patient data meta-analysis. The Lancet. 399. 249-258.
	M. G. Lansberg et al (2019). Association of Thrombectomy with Stroke Outcomes among Patient Subgroups: Secondary Analyses of the DEFUSE 3 Randomized Clinical Trial. JAMA Neurology. 76: 4. 447-453.
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	T. M. Leslie-Mazwi et al (2019). DEFUSE 3 Non-DAWN patients: A closer look at late window thrombectomy selection. Stroke. 50: 3. 618-625.
	T. M. Leslie-Mazwi et al (2019).

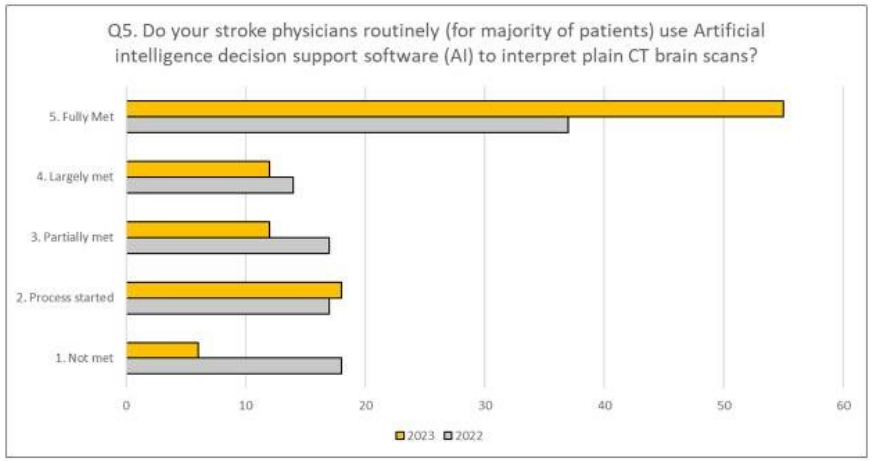
	DEFUSE 3 Non-DAWN patients: A closer look at late window thrombectomy selection. Stroke. 50: 3. 618-625.
	D. S. Liebeskind et al (2022). Collateral Circulation in Thrombectomy for Stroke after 6 to 24 Hours in the DAWN Trial. Stroke. 29: 2. 742-748.
	D. S. Liebeskind et al (2022). Collateral Circulation in Thrombectomy for Stroke after 6 to 24 Hours in the DAWN Trial. Stroke. 29: 2. 742-748.
	T. N. Nguyen et al (2022). Noncontrast Computed Tomography vs Computed Tomography Perfusion or Magnetic Resonance Imaging Selection in Late Presentation of Stroke with Large-Vessel Occlusion. JAMA Neurology. 79: 1. 22-31.
	T. N. Nguyen et al (2022). Noncontrast Computed Tomography vs Computed Tomography Perfusion or Magnetic Resonance Imaging Selection in Late Presentation of Stroke with Large-Vessel Occlusion. JAMA Neurology. 79: 1. 22-31.
	R. G. Nogueira et al (2018). Thrombectomy 6 to 24 hours after stroke with a mismatch between deficit and infarct. New England Journal of Medicine. 378: 1. Nov-21.
	R. G. Nogueira et al (2018). Thrombectomy 6 to 24 hours after stroke with a mismatch between deficit and infarct. New England Journal of Medicine. 378: 1. Nov-21.
	A. C. Peultier et al (2019). Exploring the Cost-Effectiveness of Mechanical Thrombectomy Beyond 6 Hours Following Advanced Imaging in the United Kingdom. Stroke. 50: 11. 3220-3227.
	A. C. Peultier et al (2019). Exploring the Cost-Effectiveness of Mechanical Thrombectomy Beyond 6 Hours Following Advanced Imaging in the United Kingdom.

	Stroke. 50: 11. 3220-3227.
	L. C. Polding et al (2021). Quality of Life in Physical, Social, and Cognitive Domains Improves with Endovascular Therapy in the DEFUSE 3 Trial. Stroke. 1185-1191.
	L. C. Polding et al (2021). Quality of Life in Physical, Social, and Cognitive Domains Improves with Endovascular Therapy in the DEFUSE 3 Trial. Stroke. 1185-1191.
	A. Sarraj et al (2019). Outcomes of thrombectomy in transferred patients with ischemic stroke in the late window: A subanalysis from the defuse 3 trial. JAMA Neurology. 76: 6. 682-689.
	A. Sarraj et al (2019). Outcomes of thrombectomy in transferred patients with ischemic stroke in the late window: A subanalysis from the defuse 3 trial. JAMA Neurology. 76: 6. 682-689.
	G. Turc et al (2019). European Stroke Organisation (ESO) - European Society for Minimally Invasive Neurological Therapy (ESMINT) Guidelines on Mechanical Thrombectomy in Acute Ischaemic StrokeEndorsed by Stroke Alliance for Europe (SAFE). European Stroke Journal. 4(1). 06-Dec.
	G. Turc et al (2019). European Stroke Organisation (ESO) - European Society for Minimally Invasive Neurological Therapy (ESMINT) Guidelines on Mechanical Thrombectomy in Acute Ischaemic StrokeEndorsed by Stroke Alliance for Europe (SAFE). European Stroke Journal. 4(1). 06-Dec.
	T. Ullberg et al (2022). Endovascular thrombectomy for anterior circulation stroke beyond 6 hours of onset in Sweden 2015 to 2020: Rates and outcomes in a nationwide register-based study. Journal of NeuroInterventional Surgery. 18760.
	T. Ullberg et al (2022). Endovascular thrombectomy for anterior circulation stroke beyond 6 hours of onset in Sweden 2015 to 2020: Rates and outcomes in a nationwide register-based study. Journal of NeuroInterventional Surgery. 18760.

K. S. Zachrison et al (2021). Frequency, characteristics, and outcomes of endovascular thrombectomy in patients with stroke beyond 6 hours of onset in US clinical practice. Stroke. 52: 12. 3805-3814.
K. S. Zachrison et al (2021). Frequency, characteristics, and outcomes of endovascular thrombectomy in patients with stroke beyond 6 hours of onset in US clinical practice. Stroke. 52: 12. 3805-3814.
Z. Zhao et al (2020). Efficacy and safety of endovascular treatment vs medical treatment in anterior circulation stroke beyond 6 hours: A systematic review and metaanalysis. Neurology Asia. 25(4). 439-446.
Z. Zhao et al (2020). Efficacy and safety of endovascular treatment vs medical treatment in anterior circulation stroke beyond 6 hours: A systematic review and metaanalysis. Neurology Asia. 25(4). 439-446.
Y. Zhongxing et al (2021). Efficacy and Safety of Endovascular Treatment for Acute Large-Vessel Ischemic Stroke Beyond 6 h After Symptom Onset: A Meta-Analysis. Frontiers in Neurology. 12. 654816
Y. Zhongxing et al (2021). Efficacy and Safety of Endovascular Treatment for Acute Large-Vessel Ischemic Stroke Beyond 6 h After Symptom Onset: A Meta-Analysis. Frontiers in Neurology. 12. 654816

https://assets-global.website-files.com/5faad25c38b69636dbf2667c/640a28453d2c9835a4a488c7_viz_clinical-study_validate.pdf

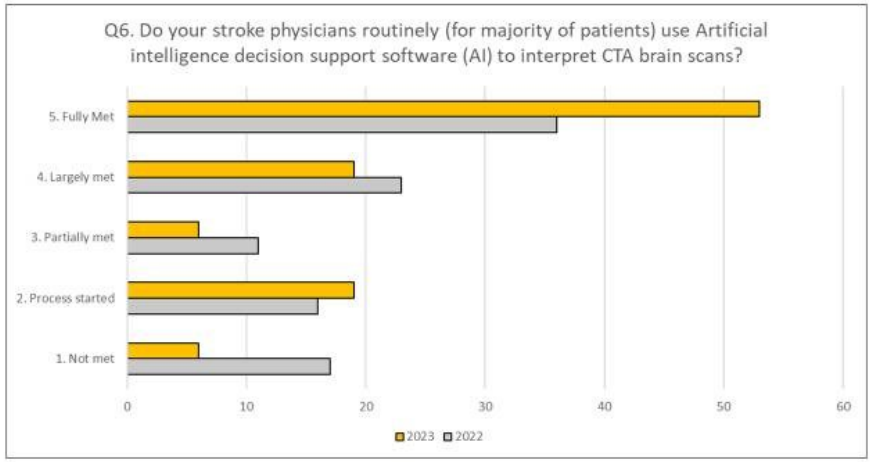
The exact number of trusts now routinely using AI (approximately 86%) which is an increase from August 2022 and we expect all trusts with designated stroke units to be using it by end 2023. The data below is from the right care tool kit self-assessment B0850-RightCare-Stroke-Toolkit_July-2022.pdf (england.nhs.uk) of all 107 stroke units in England and current as of April 2023:



AI decision support has been implemented at 99 sites with all other identified centres actively working on plans to go live before the end of 2023.

The data below is from the right care tool kit self-assessment B0850-RightCare-Stroke-Toolkit_July-2022.pdf (england.nhs.uk) of all 107 stroke units in England and current as of April 2023:

Comparison with 2022 data – AI for CTA



The procurement framework for AI decision support software, facilitated by NHS Shared Business Services, is summarised here. This is currently in active use as the remaining units/networks yet to implement this technology continue to work towards completing this by the end of the financial year.

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