AI in Health and Care Award – Final Report

Round 1 Phase 4 Final Report Template

Technology	e-Stroke by Brainomix
Technology Specific Evaluation Team (TSET) if applicable	Health Innovation Oxford and Thames Valley (previously Oxford AHSN)
Reporting Period (project start – end date)	04/21 to 03/24

PART B: TSET Section

The purpose of this report is to capture the final findings and analyses during the evaluation from the TSET.

Introduction

Background

The AAC AI Award commission was set up to run from 2021 to 2024, with the purpose of evaluating promising technologies which meet the strategic aims set out in the NHS Long Term Plan. The evidence generated by the evaluation will be used to by NICE and the UK Screening Committee to determine if the technology should be adopted.

AAC Phase 4 for "promising technology" winners, were selected based on their initial real-world efficacy, clinical and economic impact in an NHS setting; Prerequisites for Phase 4 selection were CE/UKCA marked and being at a Technology Readiness Level of 6-7.

The AAC commissioned and assigned Technology Specific Evaluation Teams (TSET) to the technology bid winners. Oxford AHSN (now renamed Health Innovation Oxford & Thames Valley) was commissioned as a TSET, to conduct a real-world evaluation (RWE) of a Phase 4 AI technology called e-Stroke, created by Brainomix.

The Technology

The sooner a stroke is diagnosed, the more quickly stroke treatment can begin; the more quickly treatment begins, the better the outcome will be. For every minute the brain is deprived of necessary blood flow, 1.9 million brain cells die.

e-Stroke provides clinicians with rapid classification of stroke type so that a patient with a diagnosis of Ischaemic stroke with large vessel occlusion (LVO) can be triaged as soon as possible for Mechanical Thrombectomy (MT).

MT is a relatively new procedure and is also known as "mechanical clot retrieval" as it involves the surgical removal of a blood clot in an artery to restore blood flow to the brain. MT is highly effective at rescuing blood flow and salvaging brain tissue, which reduces brain damage thus preventing and limiting long term disability.

e-Stroke is a CE-marked suite of tools that use AI algorithms to support the real-time interpretation of specialist radiological imaging: CT, CTA and CTP. This facilitates more patients to get the right treatment, in the right place at the right time through the quick and secure sharing of images and data. As not all hospitals provide MT, e-Stroke contributes to optimising workflow, facilitating faster transfer treatment decisions. (See figure 1 and 2)

Description and evaluation focus

The objective of Phase 4 is to explore clinical and economic impact of promising products in the NHS setting, to inform reimbursement and procurement decisions and facilitate systems adoption. The TSET has worked with the NHS sites involved in the Award to evaluate e-Stroke within routine clinical pathways to determine efficacy, accuracy and clinical and economic impact. The framework provided by the AI Award evaluation included 8 key themes which we applied to a logic model design that focused on effectiveness, value, accuracy, and safety as our main themes and with fit with site, implementation considerations, feasibility of scale up, and sustainability of scale-up as sub or cross cutting themes.

Existing evidence

There are few case studies concerning the impact of e-Stroke prior to the AI Award. An example of time saved when e-Stroke is introduced to a standard pathway in a systematic way at an Acute Stroke Centre (ASC) in the Thames Valley ISDN was studied and shown to reduce Door-In-Door-Out (DIDO) time from 140 minutes to 79 minutes. This same study also showed that clinical outcomes improved, with less disability and dependency in patients following the implementation of e-Stroke. (REF 1). Other publications are focused on the accuracy of e-Stroke in a controlled environment. (REF 2, 3, 4). This evaluation will aim to generate evidence in a real-world environment, concerning impact to clinical outcomes, specifically increased rates of reperfusion therapies and time to treatment.

Participating sites

The participating Stroke Sites were recruited via GIRFT meetings and Brainomix (the Supplier). 25 stroke sites (6 Comprehensive Stroke Centres (CSC) and 19 ASCs) in England took part in this 3-year evaluation.

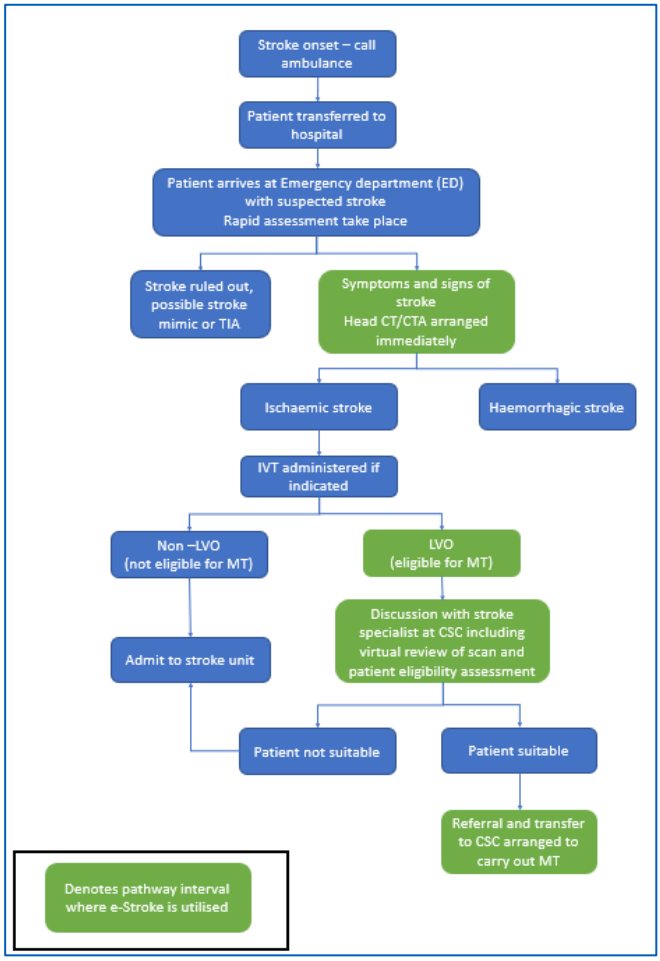


Figure 1: Simplified stroke pathway demonstrating utilisation of e-Stroke in an acute stroke centre setting.

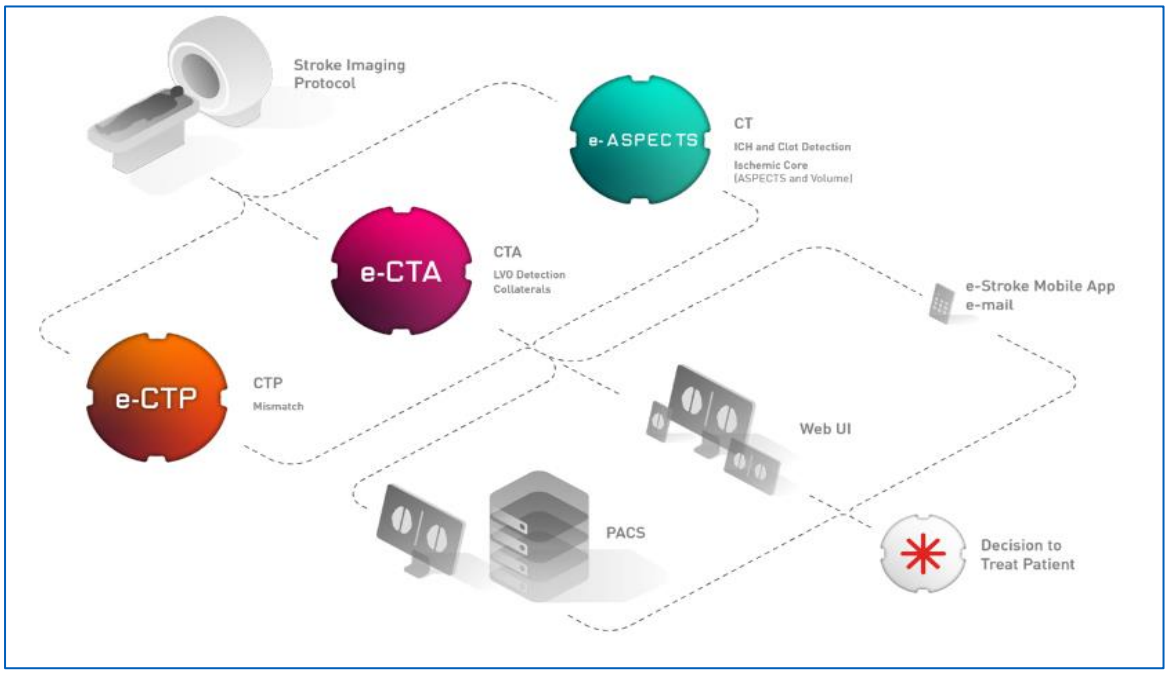


Figure 2: How e-Stroke supports imaging-based treatment pathways. Image courtesy of Brainomix
https://www.brainomix.com/media/saelwlyr/e-stroke_the-most-comprehensive-stroke-imaging-solution_web.pdf

Evaluation questions and methodology

As a real-world evaluation, we have selected a quasi-experimental approach, using a one group pre-test/post-test design. We started the evaluation with the potential to work with 31 sites that implemented e-Stroke, including 6 CSCs and 27 ASCs. However, 3 sites in Scotland have not implemented e-Stroke sufficiently to be part of the evaluation. A further 3 sites in Kent and Medway merged into one hyper-acute stroke centre (Invicta Ward, Kent and Canterbury) and 3 sites in London became rehabilitation-only centres during the period of the evaluation. The results reported here therefore concern 25 stroke sites (6 CSCs and 19 ASCs).

We have relied on an iterative approach to this multi-year evaluation, building on our findings as they emerge. It is important to note that the evaluation has spanned a period where the NHS has experienced the most severe pressures in its history. However, our hypothesis and value proposition have remained unvaried: "e-Stroke aids the interpretation of imaging in patients with suspected acute stroke and decisions for reperfusion therapies. This leads to a reduction in disability and enhanced quality of life with associated cost savings for the Health and Social Care System".

We assume that the benefits of e-Stroke are maximised through quality improvement activities, such as the GIRFT programme and establishment of the ISDNs, happening concurrently with implementation and continued use of the technology. Therefore, the findings outlined in this report can only be associated with the implementation of e-Stroke and not as a direct result of its introduction to the acute stroke pathway.

The evaluation questions, rationale and methods used to answer the questions are included in the table below.

Evaluation question	Evaluation domain (e.g. safety, accuracy, effectiveness etc.)	Rationale for inclusion and prioritisation (500 words max each question)	Methods used to answer the evaluation question (150 word max each question)	Metrics and outcomes used to answer the evaluation question (500 words max each question)

Does the technology produce the intended results? What are the outcomes for clinical, social, experiential and/or operational effectiveness?	Effectiveness	To assess if e-Stroke generates better clinical outcomes than current practice.
		
		To determine which intervals of the acute stroke patient pathway benefit from the inclusion of e-Stroke and to what extent.
		
		To assess if e-Stroke helps to identify more eligible patients for reperfusion therapy.
			Quantitative data analysis - de-identified patient level data from Sentinel Stroke National Audit Programme (SSNAP).
			
			Qualitative research and data analysis with stroke clinicians - baseline survey and individual interviews and follow up mid-term surveys.
			
			Formative feedback sessions – online workshops and meetings with stroke clinicians.
				We have investigated key intervals in the acute stroke pathway from onset of symptoms to discharge to determine if the inclusion of e-Stroke impacts time to treatment and rates of reperfusion therapy. A full list of metrics considered are available in Appendix A.
				
				The following qualitative metrics have been used to determine the perceived effectiveness of the technology by the teams using e-Stroke.
				
				• What are the benefits you are experiencing through the use of Brainomix?
				• In your opinion, has Brainomix helped to identify more eligible patients for thrombectomy?
				• In your opinion, has Brainomix contributed to a change in the number of CTA and or CTP scans performed at your hospital?
				• In your opinion has Brainomix reduced the time taken to:
				  ○ Reach a decision to administer thrombolysis?
				  ○ Start thrombolysis?
				  ○ Transfer patients for/proceed with MT?
				• In your opinion has the technology made a difference to treatment for late presenting patients?

How accurate is the AI technology in a real-world deployment environment? In a	Accuracy	To investigate the importance of accuracy and what is deemed acceptable to the stroke clinicians using e-Stroke to understand real-world impact.	Literature search and review. Qualitative research and data analysis with stroke clinicians - baseline survey and	The following qualitative metrics have been used to determine clinical confidence in the accuracy of the software:

Evaluation question	Evaluation domain (e.g. safety, accuracy, effectiveness etc.)	Rationale for inclusion and prioritisation (500 words max each question)	Methods used to answer the evaluation question (150 word max each question)	Metrics and outcomes used to answer the evaluation question (500 words max each question)
real-world setting, do the e-Stroke tools perform technically as described in a research setting?		To understand the ability of e-Stroke to complement, prompt and alert stroke clinicians in their decision to treat as a decision support tool. To understand how different clinical specialities (consultants, radiologist etc) use e-Stroke and which elements or functionality they utilise in the pathway.	individual interviews and follow up mid-term surveys. Formative feedback sessions – online workshops and meetings with stroke clinicians.	• Do you have any concerns about the accuracy of the software and which aspects of functionality does this directly relate to? • How frequently do you agree with the software? • To what extent do you trust the software to give an accurate interpretation of the scan?
What are the key risks and what assurance/management is in place? Is each module of the e-Stroke tools compliant with the most appropriate reference standard for accuracy and safety?	Safety	As the development of new therapeutics is well regulated by clinical and technology bodies, our line of enquiry will be to determine how Trusts implement a new technology to ensure that it is embedded into current clinical practice appropriately and therefore used to best effect. To understand how Trusts review and update quality assurance processes when new technology is implemented and how the safe use of the technology is upheld through appropriate execution of protocols, training and support.	Qualitative research and data analysis with stroke clinicians - baseline survey and individual interviews and follow up mid-term surveys. We will work with the technology company to understand the types of reported safety incidences and the processes and steps taken to mitigate future incidents and share learning and quality improvement opportunities between the evaluation sites and the technology company.	The following qualitative metrics will be used to determine clinical confidence in the safety of the software: • Have any informal or formal processes been introduced to support clinicians with technical issues, such as image sharing? • Have you reviewed clinical risk management processes as a result of implementing Brainomix?
What is the effect of the AI technology on current and future health and personal social care costs? How do these compare with health outcome benefits?	Value	To compare the financial effects of the AI technology against the health outcome benefits, as expressed in quality adjusted life years (QALYs).	Cost-benefit analysis to include: - the impact of Brainomix on clinical processes and outcomes, in particular the ability to undertake more MT cases, and reduction in length of stay - the value of that impact in terms of savings to the NHS and social care through more appropriate MT cases being undertaken. Our initial focus is on estimating the impact of Brainomix on clinical processes and outcomes.	A full list of metrics considered in the cost-benefit analysis is available in Appendix A.

1. Design

The figure below shows the evaluation logic model, designed and agreed with the clinical reference group.

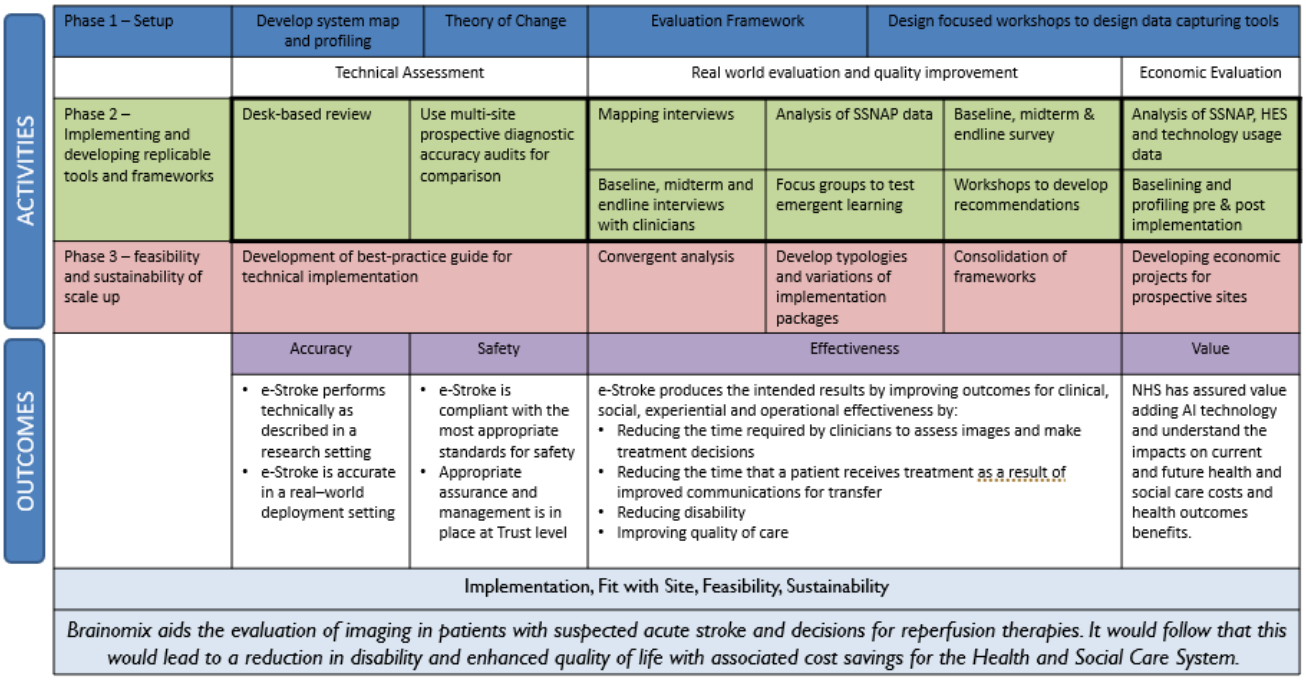


Figure 3: Evaluation logic model demonstrating evaluation phases

2. Approach

Literature and evidence review

We undertook a rapid, exploratory literature review to understand the characteristics of stroke and stroke services. Our initial review took place at the beginning of the evaluation period to provide a baseline of existing evidence and provide valuable insight into risk factors, treatment, patient outcomes and measures, rehabilitation, patient and carer experience, and associated costs of stroke to health and social care. This work has guided our approach and helped define our hypothesis.

Inevitably, during the lifespan of this evaluation, research in the treatment of patients with acute stroke and the development of AI technologies will continue, and new findings have been published. These emerging publications have been considered in our analysis.

Qualitative analysis

Our qualitative analysis has informed two main streams of our evaluation. Through cross-case analysis, we have compared commonalities and differences across sites to delineate the combination of factors that may contribute to clinical, patient, social and operational outcomes. This analysis has helped to explain why stroke services vary and to make sense of unique findings that may be considered outliers. The activities we have undertaken to provide insight into each of our evaluation sites have comprised of:

- Interviews with 17 clinicians in September 2021, representing 13 sites.
- Surveyed at the start of the project, receiving 15 individual responses, representing 11 sites.
- Surveyed 6 months after the last site had implemented, receiving and 32 individual responses, representing 12 sites.
- Pre-implementation pathway maps for 17 sites, and 11 post-implementation pathway maps, to determine variance and understand if e-Stroke has led to changes in the patient pathway.
- Profiling of hospitals based on static factors such as hospital type, patient volume, urbanicity and deprivation.

These activities have helped us to understand the perceived impact and effectiveness of the technology, identifying catalysts and barriers to implementation and sustained use through experiential feedback from stroke clinicians.

Quantitative analysis

We have received clinical audit data via the Stroke Sentinel National Audit Programme (SSNAP) at a de-identified patient level on a quarterly basis, giving us access to data from January 2019 up to March 2023, the analyses presented here are reflective of this period. We have used a pre and post-test approach focusing on key intervals in the stroke delivery pathway to determine impact of the technology on clinical and operational outcomes. This data contains 70,600 patients, 34,700 pre implementation and 35,900 post-implementation of e-Stroke. However, as hospitals had different e-Stroke implementation dates, coupled with varying caseloads, the numbers of patients undergoing reperfusion therapies can be small. Table 1.1 below shows the breakdown and incidence of stroke by age and sex, from 2019 – 2022.

Table 1.1 The age/sex breakdown and incidence of stroke 2019-2022

	2019		2020		2021		2022	
Age under 65	3450	21.1%	3559	22.7%	4167	23.9%	3771	23.2%
Age 65-79	5832	35.6%	5579	35.6%	6301	36.1%	6019	37.0%
Age over 80	7088	43.3%	6520	41.6%	6981	40.0%	6469	39.8%
Male	8508	52.0%	8210	52.4%	9274	53.1%	8623	53.0%
Female	7862	48.0%	7448	47.6%	8175	46.9%	7636	47.0%
Stroke admissions	16370		15658		17449		16259	

Formative feedback

Converging our qualitative and quantitative data and sharing this with our stakeholders at regular intervals has strengthened our evaluation approach giving us the opportunity to validate emergent findings. We have facilitated regular meetings with our clinical leads and wider stakeholder groups and have also attended regional, ISDN thrombectomy meetings, and disseminated ISDN specific reports.

Patient and public engagement

In the original evaluation plan, we planned to interact with stroke survivors, to determine whether in a real-world setting, compared to current clinical practice, e-Stroke impacted on the satisfaction of patients. Previous literature has indicated that patients with suspected stroke have limited recall of their immediate management on arrival at hospital and this coupled with our evaluation being multi-site, led to the decision not to undertake engagement with patients. Findings on our literature search on patient experience of stroke can be found at Appendix B.

Findings

Effectiveness

Key points/findings

- The use of e-Stroke is associated with an increase in patients referred for MT and therefore an increase in MT rates with 62% of clinicians agreeing that the introduction of e-Stroke has increased the number of eligible patients identified.
- e-Stroke is used to varying degrees and for different reasons, however usage has become more frequent and consistent over time.
- The use of e-Stroke is not associated with an increase in rates of IVT, however, some ASC teams will ask for decision support from the regional CSC before they proceed with IVT. This is likely to occur during discussions to decide if a patient should be referred for MT.
- Adherence to the NOSIP is key, if ASCs acquire CT and CTA images at the same time and use e-Stroke to support their decision making, the rates of IVT and MT should increase.
- The technology has improved communication within stroke teams at an ISDN level and when referring patients out of region through the efficient sharing of brain scans. There is no evidence, other than its incorporation, that e-Stroke has resulted in changes to the stroke pathway at a site level.
- The technology is used differently depending on job-role and type of site (ASC or CSC). At ASCs, e-Stroke is used more for all suspected acute strokes, as a mechanism to gain decision support from more experienced colleagues, who may be on call, working at another site or, at a CSC.
- DIDO times are being impacted on by the availability of ambulances for onward transfer to the CSC. However, we are seeing a more consistent DIDO time – i.e. a reduction in variation.
- The technology is seen to improve decision making through rapid sharing and ease of access to images, with the e-CTA module being considered very useful and of a good quality.

Methods

Quantitative data analysis - de-identified patient level data from Sentinel Stroke National Audit Programme (SSNAP).

Qualitative research and data analysis with stroke clinicians - baseline survey and individual interviews and follow up mid-term surveys.

Formative feedback sessions – online workshops and meetings with stroke clinicians.

Evaluation question: Does the technology produce the intended results? What are the outcomes for clinical, social, experiential and/or operational effectiveness?

We have focused on how use of the technology has increased the rates of reperfusion therapies, namely IVT and MT, and whether the speed at which these therapies are being delivered has improved. It is important to note that there are many factors affecting treatment and clinical outcomes such as age, gender, ethnicity and pre-existing co-morbidities and disability as well as factors affecting the efficacy of the clinical pathway such as capacity, triage, speed of ambulance response and transfer times.

The first thing to consider is how e-Stroke is used by clinicians. To determine this, we have analysed usage data (site level) and have interviewed and surveyed stroke clinicians at a cross section of the sites participating in the evaluation (clinician level).

Usage data, comparing the first 3 months use of e-Stroke to the latest 3 months, shows that 10 sites use e-Stroke more now, 2 sites usage has remained the same and 2 sites are using e-Stroke less now than at implementation. We are unable to ascertain what proportion of scans are interpreted using e-Stroke at 6 sites as all scans at these sites are automatically

processed, regardless of whether they are used in the decision-making process. This represents overall an increase from 53% of cases being interpreted by e-Stroke at implementation to 66% of scans being interpreted in our latest data (March 2023).

This is reflected in perceptions of use, as we can see that the use of e-Stroke has increased markedly, with 63.3% of respondents reporting to use the technology in more than 75% of cases (compared to 50% at baseline). Furthermore, staff at ASCs use the technology more than those at CSCs. This is to be expected, as Stroke clinicians at ASCs use the technology to support their decision-making and to communicate with the CSC teams when deciding whether to refer a patient for mechanical thrombectomy.

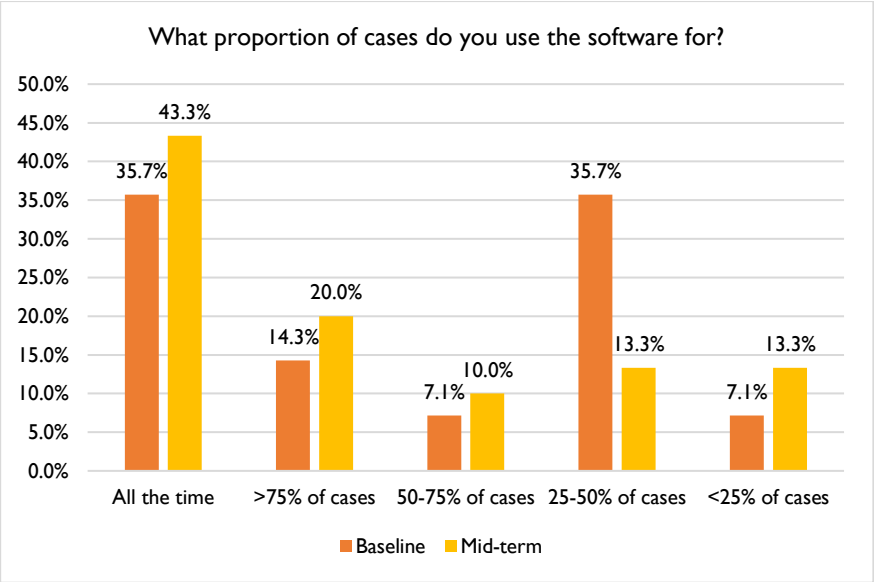


Figure 4: What proportion of cases do you use the software for? (Baseline n=15, Mid-term n=32)
Baseline survey responses obtained at the start of the evaluation, mid-term survey responses obtained at a minimum of 6 months post implementation.

ASC and CSC teams use e-Stroke comparably for potential IVT and MT cases, staff working at CSCs use e-Stroke more for patients presenting within 24 hours of onset of symptoms which is likely due to the accessibility of CTP scanning in CSCs. We can see that that ASCs use e-Stroke for all suspected acute stroke (both ischaemic and haemorrhagic) which may be because neurology expertise is less available.

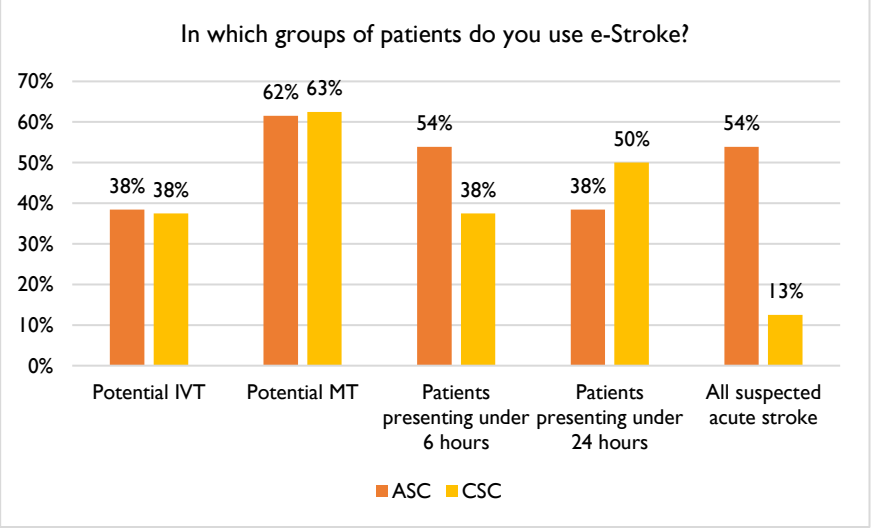


Figure 5: In which groups of patients do you use e-Stroke? (CSC n=9, ASC n=25)

Intravenous Thrombolysis (IVT)

The NHS Long Term Plan in 2019 committed to improve the use of thrombolysis and further roll out of mechanical thrombectomy to ensure that all patients admitted with acute stroke who could benefit from IVT (around 20%,) would receive it. Our analysis has shown that whilst rates of IVT vary across the evaluation, they have decreased on average from 13.2% at the start of the data collection period in January 2019 to 10.9% in March 2023, with national rates decreasing from 11.3% to 10.0%.

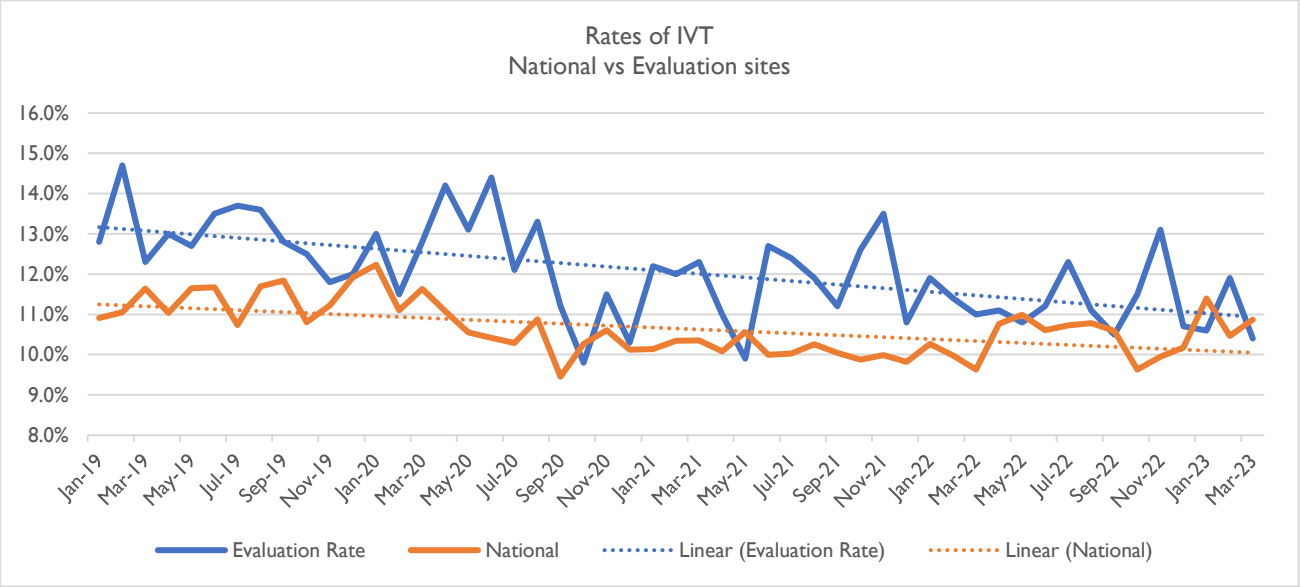


Figure 6: Rates of IVT from January 2019 – March 2023 (*Evaluation sites have been deducted from the national data)*

We understand, from our qualitative findings, that the inclusion e-Stroke in the stroke pathway does not have an impact on the decision time to administer thrombolysis. However, over a third of clinicians participating in the evaluation stated that they use e-Stroke to identify potential patients for IVT. The average rates of IVT pre and post implementation of e-Stroke remain unchanged (12.02% pre implementation, 12.01% post implementation).

Table 2.1 below summarises data from ASCs showing changes to rates of IVT and time from Scan to IVT pre and post implementation of e-Stroke.

- 9 sites have increased their rates of IVT, an increase ranging from 0.3% to 6.1%.
- 9 sites have decreased their rates of IVT, a decrease ranging from 0.2% to 3.4%.
- 4 sites have decreased the time from scan to IVT a decrease ranging from 0.5 minutes to 20.5 minutes.
- 12 sites have increased the time from scan to IVT, an increase ranging from 0.5 minutes to 10 minutes.
- 2 sites had no change to their Scan to IVT time.

It is worth noting that pre-implementation, 6 sites had a scan to IVT time of less than 30 minutes which would offer little room for improvement.

Table 2.1 Rate and time to treatment for IVT for ASCs (January 2019 – March 2023)

	Pre implementation				Post implementation				Difference	
	Number of months	No of IVT patients	Rate of IVT	Median Scan to IVT (mins)	Number of months	No of IVT patients	Rate of IVT	Median Scan to IVT	Rate of IVT	Median Scan to IVT (mins)
Colchester General Hospital	31	166	8.7	26.5	19	64	6.9	26	-1.8	-0.5
Dartford and Gravesham	20	67	9.4	37	31	128	9.7	40	0.3	3
Eastbourne District General Hospital	28	111	6.1	43	22	121	8.6	46	2.5	3
Great Western Hospital	17	75	9.5	49	33	149	9	46	-0.5	-3
Invicta Ward Kent and Canterbury	18	32	11.1	26	32	286	14.7	30.5	3.6	4.5
Ipswich Hospital	31	168	11.6	41	19	78	11.1	45	-0.5	4
Maidstone	20	94	9.6	46.5	30	264	10.6	26	1	-20.5
Milton Keynes University Hospital	15	48	16.5	22	35	91	14.5	22	-2	0
North Devon District Hospital	30	83	7.7	41	21	86	13.8	51	6.1	10
Northampton General Hospital	18	132	9.1	27	33	209	8.9	29	-0.2	2
Royal Berkshire Hospital	13	200	23.7	16.5	37	518	24.9	17	1.2	0.5
Royal Cornwall	26	169	8.8	38	25	96	5.4	48	-3.4	10
Royal Devon	24	165	9.8	31	26	175	10.3	33	0.5	2
Southend University	20	159	15.3	35	31	247	15.1	26	-0.2	-9
St Richards	27	130	12.7	35	24	138	15.4	35	2.7	0
Torbay	33	157	9.2	44	17	55	6.9	54	-2.3	10
Worthing Hospital	27	170	13.4	35	24	106	11.2	38.5	-2.2	3.5
Wycombe	17	135	11.9	25	33	295	14	33	2.1	8

Decreased scan to IVT time, Increased rates	Decreased scan to IVT time, decreased rates	Increased scan to IVT time, increased rates	Increased scan to IVT time, decreased rates

Table 2.2 below summarises data from CSCs showing changes to rates of IVT and time from Scan to IVT pre and post implementation of e-Stroke.

- 2 sites have increased their rates of IVT, an increase ranging from 0.7% to 5.4%.
- 4 sites have decreased their rates of IVT, a decrease ranging from 0.9% to 4.8%.
- 1 site has decreased the time from scan to IVT by 10 minutes.
- 5 sites have increased the time from scan to IVT, an increase ranging from 2 minutes to 31.5 minutes.

Table 2.2 Rate and time to treatment for IVT for CSCs (January 2019 – March 2023)

	Pre-implementation				Post-implementation				Difference	
	Number of months	No of IVT patients	Rate of IVT	Median Scan to IVT	Number of months	No of IVT patients	Rate of IVT	Median Scan to IVT	Rate of IVT	Median Scan to
Derriford	24	197	11.9	33	26	141	9	37	-2.9	4
John Radcliffe	18	149	15.1	31	32	386	20.5	21	5.4	-10
Queens Romford	30	403	14.1	22	20	156	10.1	25	-4	3
Royal Sussex	27	82	6.2	39.5	23	56	5.3	71	-0.9	31.5
The Royal London	25	371	17	15	25	234	12.2	23	-4.8	8
University College London	32	389	10.8	16	18	185	11.5	18	0.7	2

Mechanical thrombectomy (MT)

Our analysis has shown that whilst rates of MT vary across evaluation sites, they continue to increase despite the impact of Covid. The evaluation average has risen from 1.5% to 4.5% from January 2019 to March 2023 with some evaluation sites achieving rates more than 10%. We also know from our qualitative findings that more than half of people asked, believed that the use of e-Stroke leads to the identification of more eligible patients for mechanical thrombectomy (18/30, 7 responded 'not sure', 5 responded 'No').

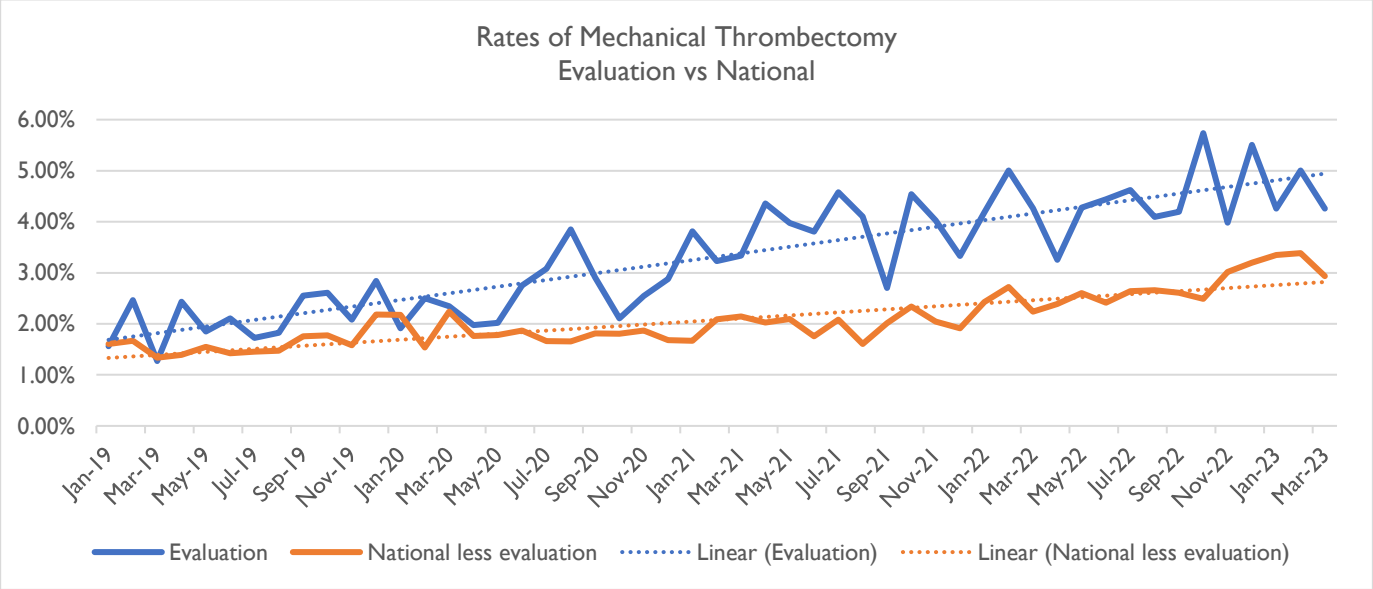


Figure 7: Rates of MT from January 2019 – March 2023 (*Evaluation sites have been deducted from the national data)*

Importantly, figure 7 shows a difference in rates between evaluation sites and national rates. The evaluation sites had an increase of 2.4% (2.1% to 4.5%) in rates of MT compared to a national (excluding evaluation sites) increase of 1.2% (1.7% to 2.9%). It is important to note that national sites were also implementing AI during this time, albeit at a slower rate and with different technologies (e-Stroke and RAPID). AI adoption has had a positive effect on MT rates in both cohorts, however, the impact of e-Stroke was significantly greater in evaluation sites (ANOVA, $p<0.001$). Whilst these findings demonstrate the benefit of AI in the stroke pathway, collaborative models of care through the establishment of the ISDNs may account for more patients undergoing MT in evaluation sites.

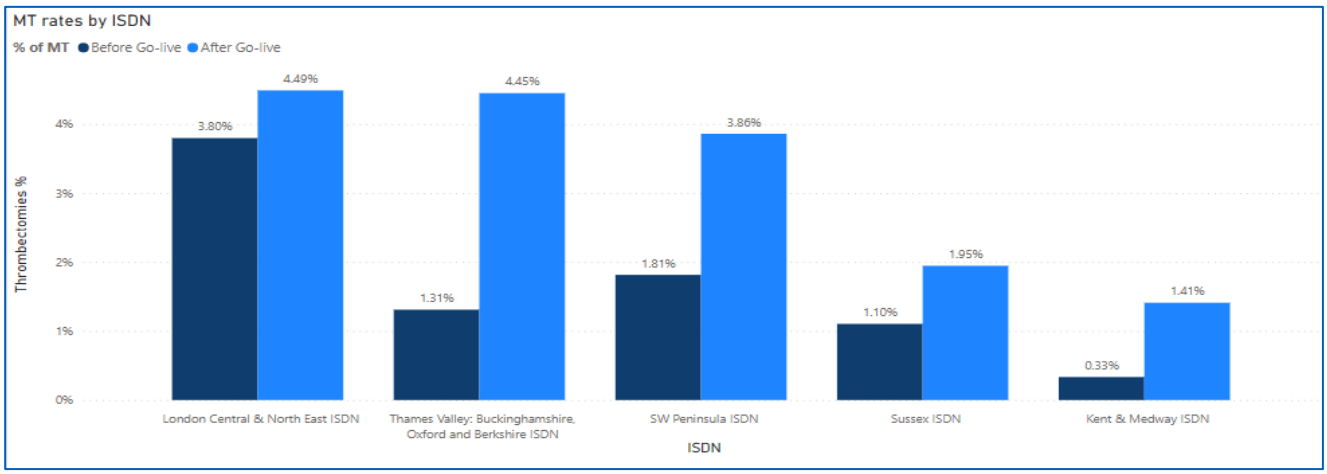


Figure 8: Rates of MT by ISDN, pre and post implementation of e-Stroke

As expected, rates of MT have increased in all ISDNs post implementation of e-Stroke (figure 8). MT activity increase was 2.1% in CSCs (4.3% to 6.4% $p=0.10$) and 1.5% in ASCs (0.9% to 2.4%, $p<0.0001$). There is a greater increase in the rate of MT in ASCs compared to CSCs over the evaluation period (figure 9), which may be associated with ASCs utilising e-Stroke in more cases than CSCs a finding from our qualitative analysis (see figure 5).

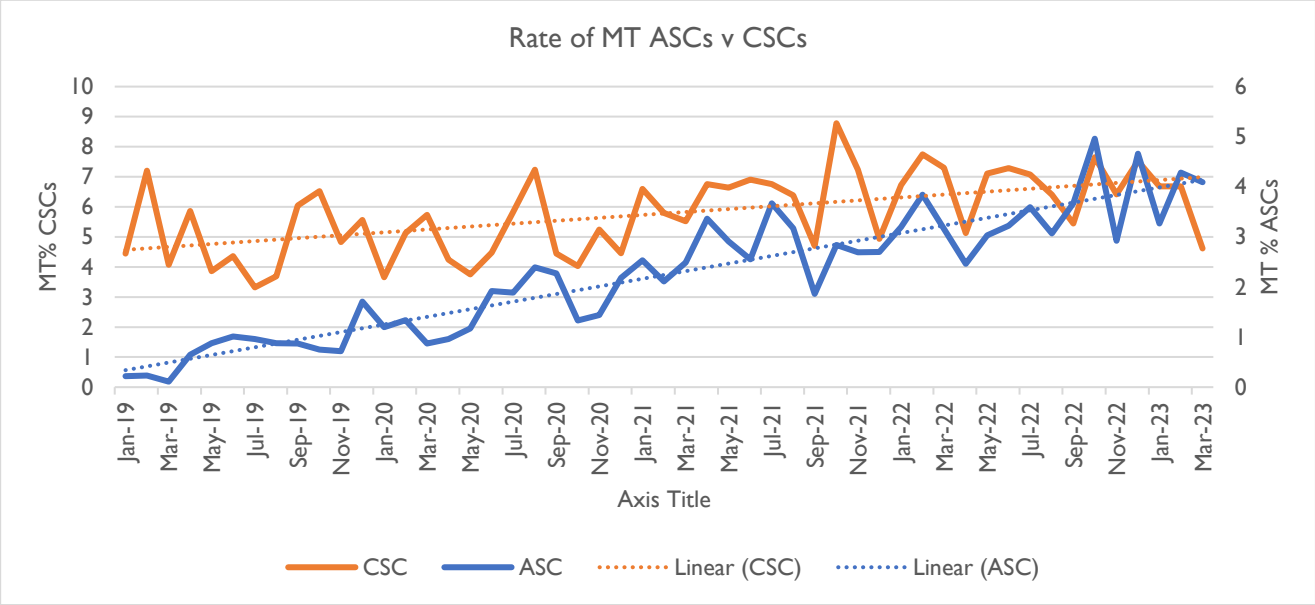


Figure 9: Rates of MT comparing ASCs to CSCs from January 2019 – March 2023

Table 2.3 below summarises data from ASCs showing changes to rates of MT and DIDO, pre and post implementation of e-Stroke.

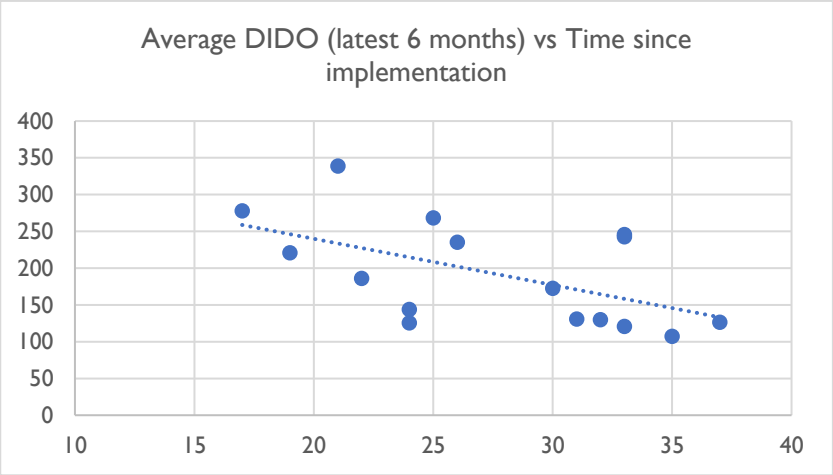
- 16 sites have increased their rates of MT, an increase ranging from 0.4% to 4.4%.
- 2 sites have decreased their rates of MT, a decrease ranging from 0.1% to 0.3%.
- 8 sites have decreased the DIDO a decrease ranging from 2 minutes to 70.5 minutes.
- 9 sites have increased the DIDO, an increase ranging from 16.5 minutes to 92 minutes.
- 1 site did not have sufficient data to demonstrate a change in DIDO.

Table 2.3 Rate for MT and DIDO for ASCs (January 2019 – March 2023)

	Pre-implementation				Post-implementation				Difference	
	Number of months	No of MT patients	Rate of MT	Median DIDO (mins) (IQR)	Number of months	No of MT patients	Rate of MT	Median DIDO (mins)	Rate of MT	Median DIDO (mins)
Colchester General Hospital	31	20	1.05	169.5 (126.5 – 194.5)	19	14	1.5	186 (162 – 209)	0.45	16.5
Dartford and Gravesham	20	2	0.28	132.5 (N/A)	31	27	2.06	158 (109-184)	1.78	25.5
East Kent University Hospitals	18	5	0.27	185 (166.5 – 193.5)	32	90	4.46	123 (92.5 – 170)	4.19	-62
Eastbourne DGH	28	0	0	0 (N/A)	22	9	0.64	138 (122-184)	0.64	N/A
Great Western Hospital	17	9	1.14	158 (122.5 – 546.5)	33	48	2.9	213.5 (156 – 405)	1.76	55.5
Ipswich Hospital	31	10	0.7	184.5 (141.5 – 229)	19	3	0.43	114 (73.5 – 170.5)	-0.27	-70.5
Maidstone	20	3	0.3	121 (103 – 131)	30	32	1.28	143.5 (111 – 200)	0.98	22.5
Milton Keynes University Hospital	15	3	1.03	93 (89 – 104.5)	35	34	5.41	91 (72 – 123)	4.38	-2
North Devon District Hospital	30	13	1.21	150 (115 – 380)	21	23	3.7	242 (140.5 – 580)	2.49	92
Northampton General Hospital	18	6	0.41	115.5 (98.5 – 127)	33	55	2.35	166 (116.5 – 237.5)	1.94	50.5
Royal Berkshire Hospital	13	11	1.3	151 (100 – 212)	37	83	3.99	91 (66 – 126)	2.69	-60
Royal Cornwall	26	17	0.88	140 (120 – 178)	25	52	2.9	175 (132 – 350.5)	2.02	35
Royal Devon	24	26	1.54	121.5 (102.5 – 173.5)	26	65	3.82	180 (121 – 382)	2.28	58.5
Southend University	20	10	0.96	239 (173 – 297)	31	40	2.44	201 (157 – 257)	1.48	-38
St Richards	27	5	0.49	190 (173 – 208)	24	14	1.56	131 (111 – 160)	1.07	-59
Torbay	33	24	1.41	183.5 (135 – 228)	17	14	1.77	137 (98 – 218)	0.36	-46.5
Worthing Hospital	27	15	1.18	110 (90.5 – 141.5)	24	10	1.06	138 (89 – 163.5)	-0.12	28
Wycombe	17	23	2.03	90 (61.5 – 130)	33	96	4.55	87.5 (65 – 127.5)	2.52	-2.5

Decreased DIDO, increased rates	Decreased DIDO, decreased rates	Increased DIDO, increased rates	Increased DIDO, decreased rates

From this analysis, we can hypothesise that sites that have been using e-Stroke for longer, have shorter DIDO times. We have further analysed this data, using the latest 6 months of DIDO data, compared to time in months since implementation of e-Stroke. Figure 10 shows this correlation.



The moderate negative correlation shown (-0.547) implies that a longer time since implementation correlates with a shorter DIDO time. A paired, two sample t-test output resulted in $p<0.00019$ confirming that this relationship is statistically significant.

Figure 10: Average DIDO from ASCs (Oct 22 – Mar 23) compared to time since implementation.

Table 2.4 below summarises data from CSCs showing changes to rates of MT and time from Scan to MT, pre and post implementation of e-Stroke.

- 5 sites have increased their rates of MT, an increase ranging from 0.1% to 6.5%.
- 1 site has decreased their rates of MT by 0.83%
- 2 sites have decreased the scan to MT, both by 11 minutes
- 3 sites have increased the DIDO, an increase ranging from 5 minutes to 22 minutes.
- 1 site did not change their scan to MT time.

Table 2.4 Rate of MT and time from scan to MT for CSCs (January 2019 – March 2023)

	Pre-implementation				Post implementation				Difference	
	Number of months	No of MT	Rate of MT	Median Scan to MT mins (IQR)	Number of months	No of MT	Rate of MT	Median Scan to MT mins (IQR)	Rate of MT	Median Scan to MT mins
Derriford	24	66	4	173 (121 – 285)	26	96	6.11	173 (115 – 408)	2.11	0
John Radcliffe	18	20	2.03	74 (57.5 – 94.5)	32	160	8.48	63 (45 – 103.5)	6.45	-11
Queens Romford	30	134	4.7	113.5 (89 – 141.5)	20	74	4.81	102.5 (78.5 – 130)	0.11	-11
Royal Sussex	27	40	3.04	67 (51 – 117)	23	51	4.8	89 (57 – 170)	1.76	22
The Royal London	25	167	7.67	101 (66 – 146.5)	25	131	6.84	106 (79 – 146.5)	-0.83	5
University College London	32	166	4.63	111.5 (83 - 132)	18	119	7.41	117 (69 – 132.5)	2.78	5.5
Increased rates, decreased Scan to MT	Decreased scan to MT, decreased rates				Increased Scan to MT, increased rates			Increased Scan to MT, decreased rates		

Onset of symptoms out of hours

We have investigated if e-Stroke is more impactful when a patient's onset of symptoms happens out of normal site opening hours (after 8pm and before 8am Monday to Friday), where there is sufficient data to analyse trends. Our hypothesis is that e-Stroke could be more effective 'out of hours' when, generally, consultant physicians are less available. e-Stroke's decision support capability and rapid image sharing function to facilitate seeking opinion from senior colleagues either working at another site or 'on call', would be particularly valuable at these times. However, the data so far shows a mixed picture, indicating that there are other factors influencing decision making. At some ASC sites, for example Royal Berkshire Hospital (figure 11 and 12), we see a marked improvement in DIDO 'out of hours' (with an average reduction of 68 mins), while there is less difference in performance 'in hours'.

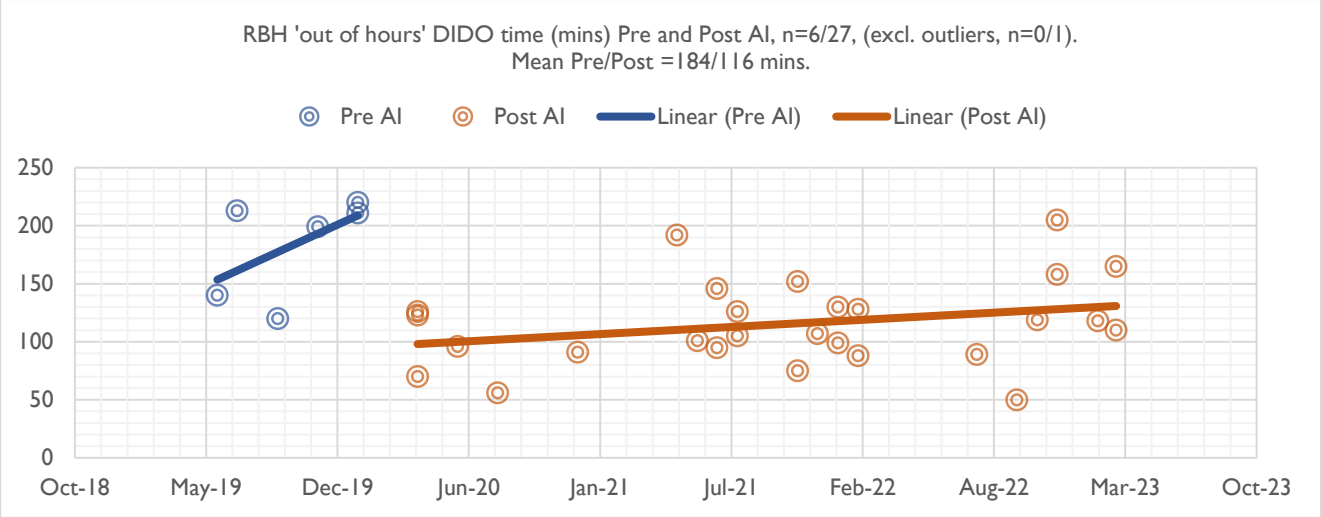


Figure 11: Royal Berkshire 'out of hours' DIDO times showing an average reduction post-AI of 68 minutes.

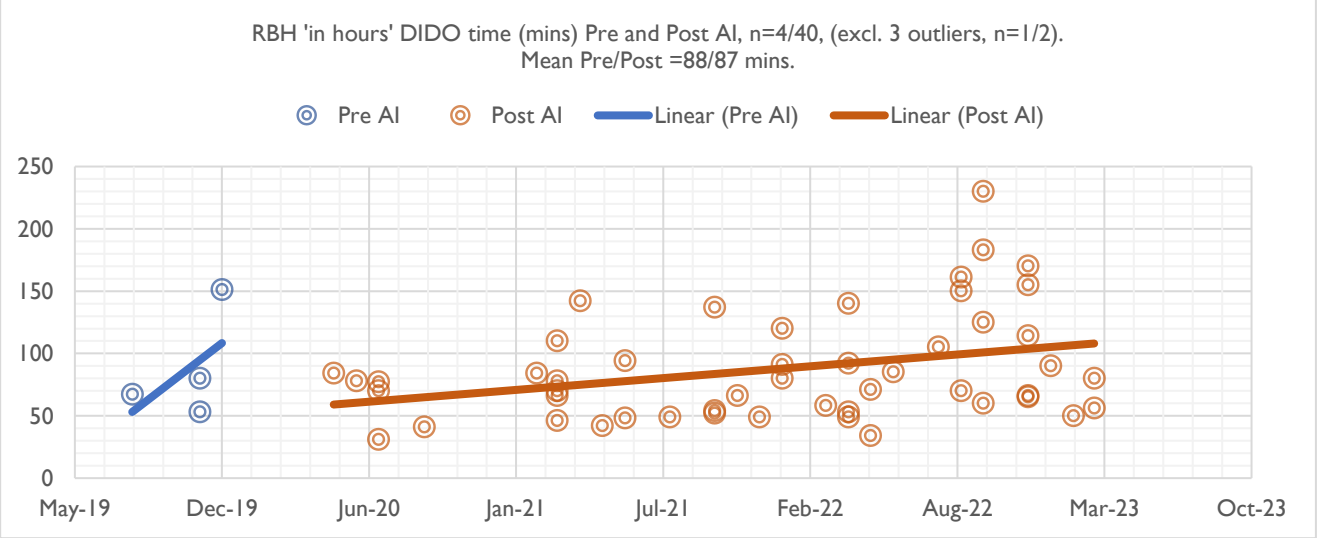


Figure 12: Royal Berkshire 'in hours' DIDO times showing little difference Pre and Post-AI.

This pattern is not observed across all ASCs. One explanation being it is likely that the more embedded and 'mature' the use of e-Stroke is at a site the more benefit that will be observed (see above analysis comparing time since implementation to DIDO). Also, due to insufficient data either Pre- or Post-AI implementation, we are not so far able to see any emerging trend. We will continue to review the impact of e-Stroke out of hours when more data is available which will be published separately to this evaluation report.

Image sharing functionality

The e-Stroke platform, including a mobile phone app and web user interface supports communication with other sites and clinicians in and out of hours, facilitating the quick and easy transfer of CT, CTA and CTP scans.

When asked what difference e-Stroke has made to how images are shared with your stroke network, the response is positive, with only 2 respondents not noting any change.

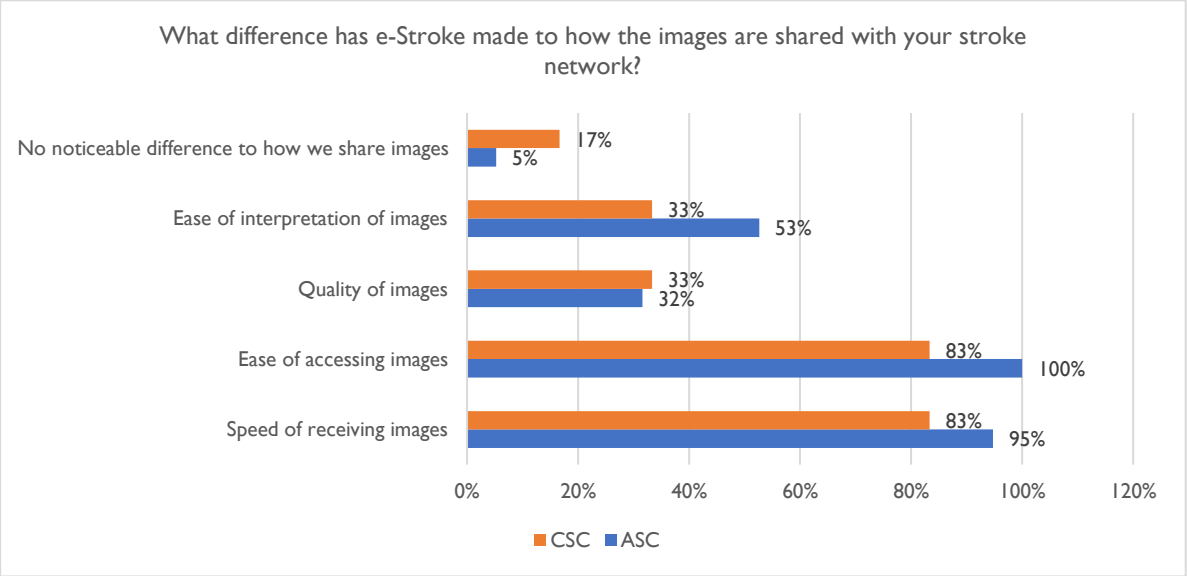


Figure 13: What difference has e-Stroke made to how images are shared in your stroke network (CSC n= 9, ASC n = 25)

As we have discussed earlier in this report, e-Stroke is used to support the identification of more eligible patients for MT and speeds up the decision to transfer to CSC for MT or proceed with MT at that site. However, the benefits of sharing images are equally if not more important, with most people citing the speed at which images are shared and received and the ease of accessing images as having a positive impact across their networks.

Accuracy

Key points/findings

- Accuracy is rightly challenged by the technology users across the evaluation. It is however accepted that the software is used as an adjunct to clinical decision making, and despite concerns with accuracy most users opt to continue using the software.

- Understanding and converging information from multiple sources are key in the clinical decision-making process. If incorporated appropriately, with the necessary training and support to ensure confidence then e-Stroke has the potential to make clinical decision making safer.

- Several studies have evaluated, in a real-world environment, how the introduction of e-Stroke can support clinical decision making. Findings signify that e-Stroke can improve the accuracy of ASPECTS scoring and the identification of occlusions for clinicians with a range of experience and backgrounds.

- Independent evaluation of decision support tools in a real-world environment is crucial to reduce the risk of bias. We recommend that new and emerging evidence is made available and spread widely to ensure that perceptions of accuracy do not impede continued use and further adoption.

Methods

Literature search and review to summarise and analyse previous and emerging research and findings into how e-Stroke performs as a clinical decision support tool.

Qualitative research and data analysis with stroke clinicians to determine real-world perceptions of accuracy and how this might affect use.

Evaluation question: How accurate is the technology in a real-world deployment environment? (Theme – Accuracy)

In this section, we will explore how clinicians using the technology perceive accuracy of the technology. We asked the following questions in our mid-term survey.

When asked "how frequently they agree with e-Stroke" 15/25 agreed with e-Stroke in more than 75% of cases, with a further 8/25 agreeing in more than half of cases.

When asked "to what extent do you trust e-Stroke to give an accurate interpretation of the scan" (1 lowest – 5 highest), of the 26 people that responded to this question, 14 gave a score of 4, 9 gave a score of 3 and 3 respondents gave a score of 2.

When asked "do you have any concerns about the accuracy of e-Stroke?", 17/28 people said they had concerns and 11/28 people said that they didn't. Of the 17 people who had concerns they were mostly regarding e-ASPECTS functionality (8). Accuracy of e-LVO, Hyperdensity identification and Haemorrhage identification were concerns for 5 respondents. One of the respondents that had responded 'Yes' to concerns with accuracy went on to comment *"Not concerns really but important to understand that Brainomix (or any other AI) is not the definitive result and will need integration with clinician and radiology opinion"*.

We have found that when there are discrepancies between clinical opinion and e-Stroke outputs, 12 of the 28 respondents reviewed and discussed images at clinical meetings and/or with Brainomix, with a few sites carrying out their own accuracy audits. However, as discussion of discrepancies doesn't seem to be widespread, this should be encouraged. Functionality within the technology allows the clinician to instantly report any concerns or conflicts of opinion directly to development teams at Brainomix for further investigation.

Brainomix continue to refine the algorithms and technology to improve standalone performance and continue to monitor real-world performance and for this reason, sites should ensure they are utilising the most recent version of the technology available to them. This does, however, pose a problem in many Trusts that require internal authorisation when software upgrades are required, meaning that some Trusts only comply with major version changes.

Education and training, as expected, is key, particularly to manage the expectations of the users and potential users regarding the intended use.

Evaluation question: In a real-world setting, does the technology perform technically as described in a research setting? (Theme – Accuracy)

Whilst our qualitative findings suggest that accuracy is challenged, it is accepted that the software is a clinical decision support tool. There are a significant number of studies evaluating the standalone performance of AI in stroke care, compared to the ground truth, normally determined by a specialist clinician. It is important to understand how the software can improve diagnostic accuracy when used alongside a clinician as a decision-support tool. The following studies aimed to quantify this effect.

- When clinicians use e-ASPECTS to support their decision making, the accuracy of ASPECTS scoring improves significantly, even by expert neurologists and neuroradiologists (Kobeissi et al, 2023 (REF 5))
- Using e-CTA as a decision support tool to determine cerebral collateral circulation both improves accuracy and reduces the time taken to score for clinicians with a range of experience and training backgrounds (Jabal et al, 2023 (REF 6))
- The use of e-ASPECTS in emergency departments with non-stroke specialist clinicians improves performance similar to that of a neuroradiologist, potentially increasing the number of patients treated with reperfusion therapies (Scavasine et al, 2022 (REF 7))

A recent real-world evaluation of e-Stroke conducted at UCLH, used a consecutive unselected cohort of patients, analysing data from a wider range of patients that are likely to be admitted to a stroke unit. (Mallon et al, 2023 (REF 8))

- As a clinical decision support tool, e-Stroke provides rapid and reliable analysis of CT scans.
- e-Stroke successfully processes over 97% of scans in an average time of 4 minutes.
- e-ASPECTS had an accuracy of 77% for identifying acute middle cerebral artery territory ischaemia and 69.1% accuracy for identifying hyperdense thrombus.
- e-ASPECTS is more than 97% accurate at identifying acute hemorrhage.
- The accuracy of e-CTA for identifying large vessel occlusion was 91.5%.

Safety

Key points/findings

- e-Stroke is CE-marked and FDA-cleared with each module being compliant with DCB0129.
- e-Stroke is registered as a Class 2b device as per IMDRF categorisation.
- A system approach to implementation has been used by most sites in the evaluation, ensuring that multiple activities take place to ensure the safe adoption of the technology with training and key stakeholder engagement being the most widely used.
- Brainomix provide comprehensive implementation support that is recognised by the system as robust and of high quality.

Methods

Desk based research into regulatory requirements and assessments.

Qualitative research and data analysis with stroke clinicians to determine real-world perceptions of accuracy and how this might affect use.

Evaluation question: Is each module of the e-Stroke tools compliant with the most appropriate reference standard for accuracy and safety?

Our desk-based research concluded that e-Stroke is a CE-marked and FDA-cleared collection of tools with each module being compliant with DCB0129 Clinical Risk Management. It is classified as a Tier C digital technology, to inform and drive clinical management (REF 9), and a Class 2b device as per IMDRF categorisation. Furthermore, risk mitigation tools are in place and functioning and include training, user authentication, patient non-identifiability and functionality within the software that facilitates feedback loops between user and developer.

Evaluation question: What are the key risks and what assurance/management is in place? (Theme – Safety)

At a site level, it is important that the users of e-Stroke are aware of the limitations of the technology and are responsible for its safe inclusion in the stroke pathway. The main risk is if the software is used to decide on treatment for a patient in isolation, without a healthcare professional review taking place. As previously mentioned, our qualitative findings confirm that the teams using e-Stroke understand that it is a decision support tool and is used in conjunction with clinical data and expertise to determine a patient's prognosis. It is also recognised that the software is used to identify patients' eligibility for reperfusion therapies and therefore used predominantly by stroke physicians, rather than radiologists to determine next steps. Awareness of how the software can support clinical decision making is clear and generally understood.

A key aspect of assurance and safety is to ensure that technology is implemented and embedded successfully into normal clinical practice. We have found that a variety of activities have been adopted to ensure the seamless implementation into existing stroke pathways, with training for staff and key stakeholder engagement being the most widely used.

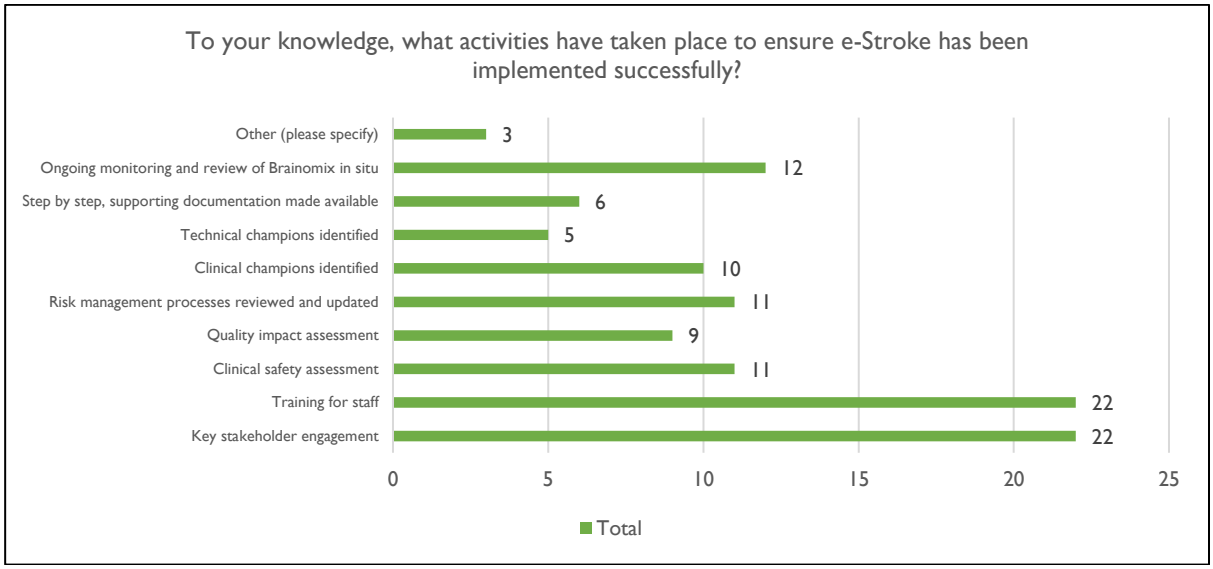


Figure 14: What activities have taken place to ensure e-Stroke has been implemented successfully (n=29)

These findings suggests that a system approach to ensuring the technology is embedded safely has been used across sites. Additionally, the supplier conducts an extensive implementation process to ensure that, rather than relying on a single activity, a series of activities takes place from the initial kick-off meeting when detailed risks are assessed pre-installation, to communications, training and ongoing monitoring and review post installation.

Training plays a significant part in ensuring the technology is implemented appropriately but also in its continued safe use. The team at Brainomix have been highly praised for the training with over 80% (26/32) of all staff saying they are satisfied or extremely satisfied with the training provided. User training is provided onsite and virtually (with sessions recorded) and the opportunity for detailed questions and answers and is scheduled with the clinical lead and all potential users of the technology including radiology and associated stroke teams. The training includes:

- Detailed showcase of the features by module
- Hands on training with actual patient results produced in the hospital on all image viewing modalities utilized by e-Stroke (PACs, web interface and smartphone app).
- After go-live the supplier and clinical lead review the first processed cases and find tune configuration if needed
- All training is logged, and users trained sign off on attendance.
- Follow-up training can be scheduled after go-live to review further cases.
- The supplier provides ongoing maintenance and support which includes a review 30 days post implementation to confirm that installation is satisfactory.

One site has produced a practical guide to support clinicians at various stages of the stroke pathway, with the process of image sharing. This shows that there is great potential for sites to collaborate more closely with the e-Stroke team to facilitate access and use.

Further discussion on implementation is included later in this report and should be considered alongside these findings (cross-cutting themes).

Value

Key Points

- Within the context of a good ambulance service, e-Stroke is associated with an increase in the rate of patients undergoing MT by around a third from 2.3% of all strokes to 3.1%.
- Within the context of a good ambulance service, e-Stroke is associated with an increase in the number of patients receiving thrombolysis by a proportional rate of 16% increasing the rate from 12.8% to 14.9%.
- e-Stroke appears to reduce the amount of time from imaging to treatment by some 3 minutes.
- In financial terms, the benefits, which accrue to social care, are of the order of 1.4 times for our base case scenario (since £124.5k ÷ £86.8k = 1.43), 1.35 times for our optimistic scenario versus costs (£141.8k ÷ £105.3k = 1.35), and 1.25 times for our pessimistic scenario versus costs (£83.0k ÷ £66.4k = 1.25) (see table 2.5 below).
- Health benefits are valued at 1.35 times costs in addition to the financial benefits for optimistic and base case scenarios, and 1.17 times costs for the pessimistic scenario.

Methods

Cost benefit analysis (HM Treasury Green Book), assessing base case, optimistic and pessimistic scenarios (REF 10). Regression analysis to determine the impact of the technology on stroke outcomes.

Evaluation question: What is the effect of the AI technology on current and future health and personal social care costs? How do these compare with health outcome benefits?

A summary of the cost benefit analysis is presented below. The full Value report can be accessed at Appendix C.

Table 2.5 is a summary of benefits for a hypothetical hospital with 600 patients admitted for stroke per year, based on our findings. This is representative of the average number of patients per year per site from 2019 to 2022 for the 24 hospitals in our evaluation. The summary presents two scenarios – a base case where benefits and costs align with an increase in thrombolysis and MT treatments. This agrees with that observed through our statistical analysis (from 2.3% percent to 3.1%) and an optimistic scenario, in which benefits and costs are augmented by a further increase in MT cases (to 3.5%), that we have seen exceeded in 2022 at the following sites: John Radcliffe Hospital (12.1%), University College London Hospitals (7.8%), Milton Keynes University Hospital (7.59%), The Royal London (6.69%).

Benefits for patients who are treated each year are assessed over a five-year period and relate to (a) increased numbers of patients enabled to be discharged to home multiplied by the unit saving from 0.65 to 0.85 staying at home rather than entering a care home; and (b) incremental health benefits as assessed in QALY terms multiplied by a value of £20,000 per QALY.

Costs relate to the costs of treatment (Balami et al, REF 11) and (The National Guidelines Centre and SSNAP, 2016 Cost and cost-effectiveness: technical report) respectively on the additional cost of stroke patients being treated with MT and/or thrombolysis procedures compared to standard stroke patients. This is multiplied by the additional number of treatments being undertaken (estimated at £51k to £88k), and cost of the technology, initial training, and implementation costs (estimated at £21k, based on data provided by Brainomix, the e-Stroke company).

Table 2.5: Summary of costs and benefits for cohort over 5-year period– indicative illustration based on study findings for a hypothetical hospital (Single Site) (2022/23 prices)

Single Site	Base case scenario[1]	Optimistic scenario	Pessimistic scenario
Benefits	£	£	£
Social care (financial)	*£124,500*	*£141,800*	*£83,000*
Health benefits (non-financial)	*£117,200*	*£141,800*	*£77,500*
Overall benefits	*£241,700*	*£283,600*	*£160,500*
Costs			
Extra costs of treatment (financial)	*£65,900*	*£88,400*	*£45,500*
Technology and training costs	*£20,900*	*£20,900*	*£20,900*
Overall costs	*£86,800*	*£105,300*	*£66,400*

In financial terms, the benefits, which accrue to social care, are of the order of 1.4 times for our base case scenario (since £124.5k ÷ £86.8k = 1.43), 1.35 times for our optimistic scenario versus costs (£141.8k ÷ £105.3k = 1.35), and 1.25 times for our pessimistic scenario versus costs (£83.0k ÷ £66.4k = 1.25).

Health benefits are valued at 1.35 times costs in addition to the financial benefits for optimistic and base case scenarios, and 1.17 times costs for the pessimistic scenario.

It should be noted that the optimistic scenario, though worthwhile, has a lower benefit cost ratio than the base case. This is because it relates to an expansion of Mechanical Thrombectomy treatments, which have a higher cost than thrombolysis treatments (whose volume stays the same in the two scenarios). The lower ratios for the pessimistic scenario are due to lesser efficacy.

Fit with Site

Evaluation question: Is the technology addressing the sites' requirements and population needs? Is the technology acceptable to clinicians?

e-Stroke has been implemented in sites that have an acute or hyperacute stroke service, therefore meeting the site and population needs. Each stroke unit is configured differently with differing pressures such as access and capacity of the clinical teams and the environments that they work in. Despite this and considering an initial period of embedding we have observed a continued and consistent use of e-Stroke across the evaluation, demonstrating acceptability to clinicians. When asked, more than two thirds of users (22/32) reported to liking the software (10 Really Like, 12 somewhat like). e-Stroke is however, not currently seen as an essential technology in the acute stroke pathway with a number of clinicians feeling neutral about e-Stroke (8) and a minority being sceptical (2).

Stroke clinicians have reported overall that there are many benefits to the introduction of e-Stroke in the acute stroke pathway, valuing the improved image sharing and quick diagnosis and decision to treat the greatest.

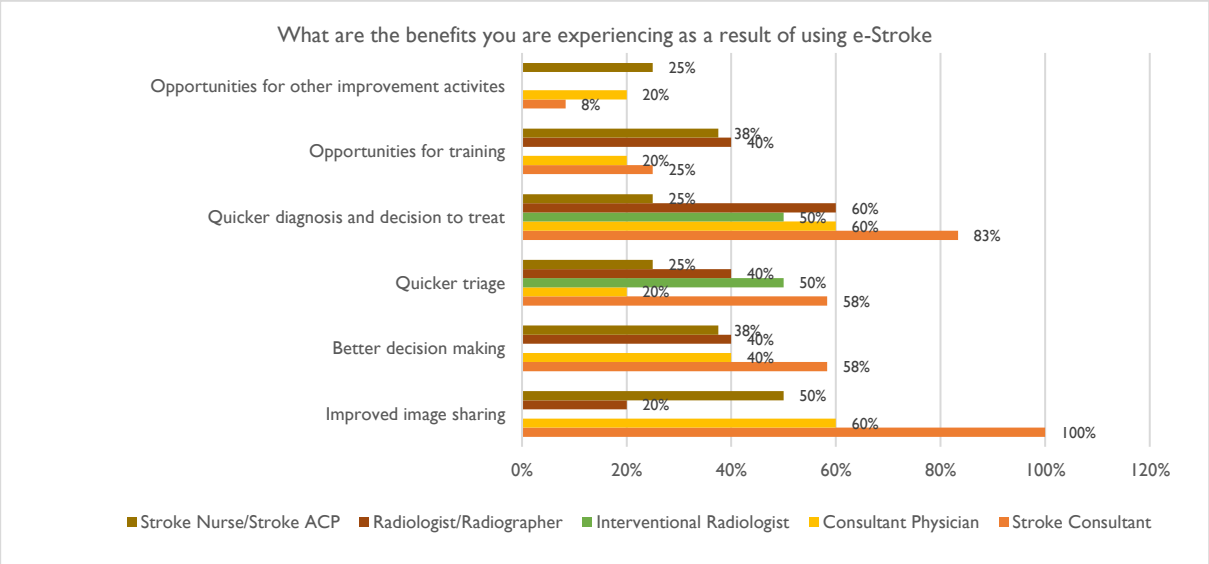


Figure 15: What are the benefits you are experiencing as a result of using e-Stroke? (Stroke Consultants n=12, Consultant Physician n=5, INR n=2, Radiologist n=5, Stroke Nurse/ACP n=8)

When asked if e-Stroke has met expectations in terms of operational outcomes so far, of the 30 people that responded, 8 said completely, 20 somewhat and 2 not at all. This is an improvement from the baseline survey in which 6 out of 14 respondents answered no.

A testament to how well the technology has been received is to whether people want to continue using it and when asked, 25/28 people said they would personally want to continue using e-Stroke post the trial period.

"I find it a very useful adjunct that helps me report with increased confidence"

"Very valuable"

"Imperative to have this resource (or similar) for rapid interpretation of acute stroke imaging and transfer"

"Brilliant for referrals and governance"

"It is absolutely essential for a rural ASC to have a rapid imaging interface with London MT services"

"Considering half of our MT cases present out of hours, e-Stroke will continue to help reduce delay to decision making for referral to tertiary unit"

"e-Stroke is a useful tool even of experienced clinicians."

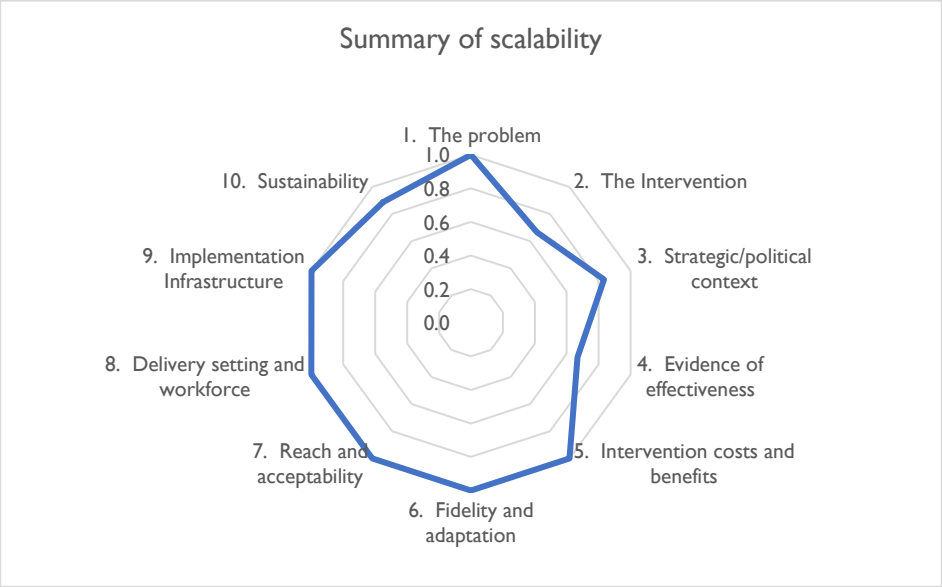
Feasibility of scale-up

Evaluation question: What is the scaling strategy and how is adaptability ensured?

'Scalability is the ability of a health intervention shown to be efficacious on a small scale or under controlled conditions to be expanded under real-world conditions to reach a greater proportion of the eligible population, while retaining effectiveness' (Milat et al, 2013 REF 13).

As this is a Phase 4 technology, we are evaluating the expansion of the technology to multiple sites to determine effectiveness. A horizontal or stepwise approach to scale-up has continued to non-Award sites concomitantly, with evaluation findings used to support and help refine further roll out. e-Stroke is now in use in more than half of the stroke centres in England (77/107).

We have conducted an intervention scalability assessment which identifies and considers contextual factors that may help or hinder scale-up and provides a structure to determine whether the technology is scalable. Details of the assessment, based on Milet et al toolkit, can be found at Appendix D. We have found that e-Stroke merits scale up.



Page 26 Figure 16: Intervention Scalability Assessment Radar Plot based on Milet et al toolkit.

Implementation considerations

Evaluation question: What activities are required to ensure fidelity of implementation?

There are many factors associated with effective implementation, and as this is a cross-cutting theme, we have explored and discussed some of these earlier in the report. There is a thorough approach to implementation by the technology partner, discussed under our safety theme. Crucially, stroke clinicians have expressed satisfaction with training and support received from Brainomix at implementation (26/27).

When asked more specifically about factors that have hampered the implementation and use of e-Stroke the following were given as reasons:

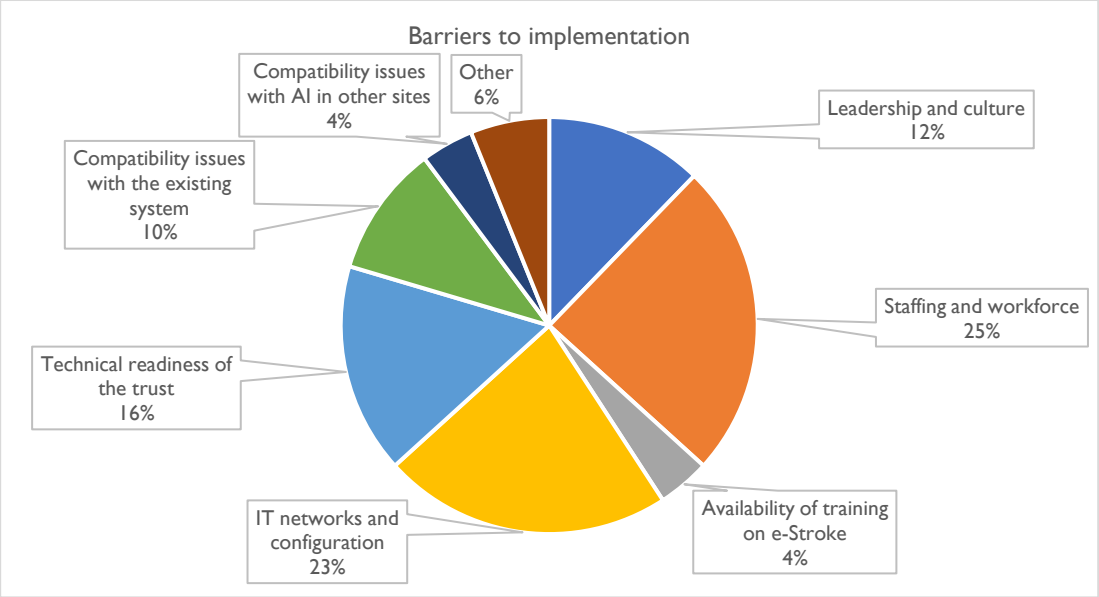


Figure 17: Barriers to implementation (n=23)

We have grouped these responses under three broad headings, technical (readiness of the trust, IT networks and configuration and compatibility issues), social (staffing and workforce, training) and organisational (leadership and culture).

Technical considerations

"To work with teams that have this up and running…. specifically with respect to technical issues"

There have been several occasions where the users of the system have contacted the technology partner for matters relating to network and configuration which is managed by the Trust. It is important to understand and confirm roles and responsibilities during planning and implementation.

There have also been issues with upgrades, where a Trust needs to gain approval for an upgrade to the system is required. Appropriate planning should take place to ensure prior agreement with Trust IT departments that upgrades are essential and do not require repeat approval to ensure that these happen in a timely manner.

"Excellent investment but synergy with thrombectomy centre from day is invaluable"

"Select the software solution jointly with your referring units to guarantee maximum buy- in."

Currently, differing AI platforms are not interoperable, so transfer of images from an e-Stroke site to a site that has implemented another technology has issues. One solution could be that the thrombectomy centres have access to both/all technologies, so that the rapid transfer of images and decision-making process is not delayed by the technology.

Social considerations

"Need to engage all stakeholders, and especially radiology and IT"

One user of the technology, a consultant radiologist, stated that the implementation of e-Stroke had changed demand on stroke imaging with the introduction of routine CTA scans for all stroke patients and that this had increased demand on acute reporting services. This, however, is also a recommendation of the NOSIP (REF 14) that CT and CTA scans are acquired at the same time for suspected acute stroke.

"Make sure it is accurate in the real world before buying"

As discussed earlier in this report, there are concerns with accuracy of the tool. Education and training are key to manage expectations of accuracy and build consensus on its use as a decision support tool.

"Training is key. At the end of the day, training of the reporting radiologist on how to interpret the imaging properly is the most important factor in patient care, as the radiologist will have to judge whether the AI is right or wrong, because they take ultimate responsibility for the final radiology report."

Furthermore, dissemination of emerging research, both controlled and real-world, should be shared to ensure the fidelity of scale-up, ensuring that new adopters of the technology have clarity of the problem the technology has been designed to tackle and therefore benefit in the same way as evaluation sites have.

Organisational considerations

Most evaluation sites said that they had identified clinical champions to ensure effective implementation, however the responsibility should not just be with one person i.e. not just leadership, but user ownership.

Expectation of the impact of the technology should be realistic, as previously discussed, the main function of the software is to increase identification of eligible patients for MT and expedite treatment. It is not expected to replace parts of the pathway or radiological expertise but to support stroke consultant's referral decisions.

Whilst we have seen significant improvements in the rates of patients undergoing MT at our evaluation sites, time to treatment has not been impacted as much. Factors such as availability of MT services (both distance to CSC and opening hours) and availability of CTP should be considered at implementation as both have been shown to impact the effectiveness of e-Stroke.

"It depends how we look at this (factors that might limit the impact of e-Stroke). If we assume the main impact of Brainomix is improving pathway efficiency, yes, the delay in secondary ambulance transfer, the lack of availability of MT services requiring us to call multiple centres to refer patients did limit the impact of Brainomix."

Sustainability of scale-up

Evaluation question: How is sustainability and continuity of scale-up ensured?

Stroke is a leading cause of death and disability in the UK. Between 2015 and 2035 the number of strokes in the UK per year is projected to increase by 60% and the number of stroke survivors is projected to more than double (Patel et al, 2020 REF 15). The need to quickly identify and refer patients for MT will grow comparably. When asked what factors might limit e-Stroke, the following responses (availability of ambulance, CTP and MT services) were the most common.

"There have been operational pressures in ambulance services that have delayed transfer"

"Distance to tertiary centre where MT is performed….. availability of ambulance crews"

"Availability of MT" and *"Availability of CTP"*

These confounding factors which are also confirmed as significantly impactful through our regression analysis (Appendix C) may delay sites realising the full benefits of the software. Interestingly, neuro-radiologists have commented that any AI software should be able to assist with radiology workload. As e-Stroke is only currently used to support decision to refer patients for MT, this holds great potential for sustainability of e-Stroke as an integral part of the stroke pathway, creating a wider recognition of the tool and acceptability amongst radiology specialists.

The cost benefit analysis carried out has demonstrated significant value to the introduction of the technology, even if only small increases in the number of patients receiving MT are associated with the use of e-Stroke. There are other, social and organisational benefits to be realised, the most important of which is improved communication between clinicians and stroke teams at different sites (26/32). The introduction of AI in the stroke landscape has been cited as raising the profile of stroke, potentially making it a more attractive specialty to work in and as two thirds of stroke clinicians (16/24) reportedly feel more confident in their decision making, could be associated with staff satisfaction and retainment. It is clear from our qualitative work that e-Stroke is considered a critical friend for stroke physicians working at ASCs, particularly in times when they might be the only stroke specialist available.

"Improves communication, empowers teams and individuals, raises the profile of stroke medicine and innovation in your hospital"

"Raised profile of stroke locally with media interest in the product"

A holistic approach to sustaining scale-up of any new technology is vital (REF 16). Targets for rates of IVT and MT alone will not ensure continued use of the technology and other approaches, such as commissioning frameworks (AI Software in Neuroscience for Stroke Decision Making Support (REF 17)) that articulate healthcare priorities and create opportunities for innovators should be employed to sustain spread. The Getting in Right First Time (GIRFT) review of stroke services made a series of recommendations, after meeting with 122 acute stroke services across the country, calling for system-wide working delivered by the ISDNs and encouraging the use of AI to optimise the stroke imaging pathway and support rapid access to imaging.

"The use of artificial intelligence (AI) in stroke care should be encouraged and deployed in line with its certified and pre-specified use or within a research environment. Image sharing between centres within and external to each ISDN should be optimised to provide timely patient-centred decisions and align with ICS imaging networks."(REF 18)

The final recommendation for sustainability of scale therefore refers again to the interoperability of disparate systems to enable rapid image sharing.

"Make sure that all of the local hospitals sign up to the same AI software. One of our MT providers uses different software and are not keen to use Brainomix cases that are sent."

Conclusions

Effectiveness

We found that e-Stroke is associated with a significant increase in rates of MT and a reduction in DIDO times at ASCs. There is a relationship between time since implementation and time to treatment, with ASCs using e-Stroke for longer observing a bigger decrease in DIDO time.

Qualitative findings suggest that e-Stroke is not systematically used to identify patients for thrombolysis which may be why rates of IVT and time to IVT to do not appear to be affected by the introduction of e-Stroke.

Accuracy and Safety

The technology is seen as straightforward to use and reliable, processing over 97% of scans in an average time of 4 minutes. e-Stroke is perceived as a useful clinical decision support tool and despite some concerns with accuracy, most clinicians opt to continue using the software with use increasing over time. Other studies investigating how the introduction of e-Stroke supports clinical decision making have found that e-Stroke improves the accuracy of ASPECTs scoring and the identification of LVOs of clinicians with a range of experience and backgrounds.

A systems approach to implementation has been adopted widely, ensuring that multiple activities such as training, stakeholder engagement, quality impact and clinical safety assessments, assure the safe adoption of the technology. The technology company are praised for providing comprehensive support that is recognised by the system as robust and high quality.

Value

e-Stroke is associated with a financial benefit in the region of 1.25 to 1.4 times the cost of implementing the technology, and with health benefit in the region of 1.17 to 1.35 times the cost of implementation.

Fit with site, feasibility and sustainability of scale-up

The continued and consistent use of e-Stroke across evaluation sites demonstrates acceptance and usability by clinicians, with many benefits being noted to its introduction and we have found that e-Stroke merits scale up. e-Stroke demonstrates significant value to stroke services and as the number of patients having a stroke is projected to increase substantially in the future, AI decision support will be an essential adjunct to clinical expertise.

Implementation considerations

Engagement and training with all stakeholders and potential users of the technology is key to implementation. Expectations of the impact of the technology should be realistic – e-Stroke is not intended to replace any part of the stroke pathway or radiological expertise but as an addition to specialist clinical expertise. Radiology clinicians reported concerns about the increasing number of scans generating more workload, but this could be associated with better adherence to the NOSIP rather than solely through the introduction of e-Stroke. Implementing e-Stroke at a network level, rather than individual sites will ensure effective adoption.

Recommendations and future research

Independent evaluation of decision support tools in a real-world environment is crucial to reduce the risk of bias. We recommend that new and emerging evidence is made available and spread widely to ensure that perceptions of accuracy do not impede continued use and further adoption.

Dissemination

Throughout the evaluation we have attended the following meetings on a regular basis to engage with stakeholders and share emerging findings from the evaluation.

- South East Oversight Group.
- TiTAN group/ BOB ISDN.
- Sussex ISDN Thrombectomy Group and Rehabilitation and Life After Stroke Steering Group.
- South East Clinical Leads Group.
- Southwest Regional Thrombectomy Group.
- Southwest Peninsula Oversight Group.
- London Thrombectomy Group.

We have released a number of documents including:

- ISDN specific reports
- The interim evaluation report (September 2022) https://www.oxfordahsn.org/our-work/adopting-innovation/digital-health/ai-award-evaluation-of-e-stroke-interim-findings-september-2022/https://www.oxfordahsn.org/our-work/adopting-innovation/digital-health/ai-award-evaluation-of-e-stroke-interim-findings-september-2022/
- We collaborated with Brainomix to produce an animation highlighting the key findings from the interim report https://vimeo.com/847892114
- The annual evaluation report (March 2023) https://www.healthinnovationoxford.org/wp-content/uploads/2023/06/OAHSN-Evaluation-of-e-Stroke_Annual-Report_March-2023_FINAL.pdf

Members of the team have also attended various events and webinars to present and share the evaluation activities and findings.

- Shared learning days hosted by Brainomix.
- Webinars hosted by Brainomix.
- A webinar hosted by Health Innovation Oxford & Thames Valley facilitated by Dr Kiruba Nagaratnam and Dr David Hargroves.
- Presentation at the South East Stroke Quality Improvement Forum.
- Attendance and presentation with Dr Paul Bhogal (The Royal London) and Riaz Rahman (Brainomix) at the SBRI AI Award Annual conference.

Dissemination plan from March 2024 (these items are subject to change)
As the evaluation concludes we plan to produce the following documents to disseminate the findings and recommendations of the evaluation.

- Final evaluation report.
- Case studies and online documents covering the eight themes including:
    - Reasons for not administering IVT.
    - Scan to AI referral.
    - The impact of AI for patients who have a stroke out of hours.
    - AI as a decision support tool- what needs to be considered? With a focus on accuracy and safety.
    - An overview of results of our value assessment.
    - A review of how to effectively implement AI.
    - How to understand if the impact of technology is replicable.
    - Cohort profiles and quality improvement.
    - The use of AI within the stroke pathway.
- Submission of abstracts to Stroke conferences.

All previously released and planned documents of the evaluation findings will be made available via a dedicated webpage hosted by the Health Innovation Oxford and Thames Valley's. This webpage will also be shared though our organisations social media platforms and newsletter.

We will attend relevant forums to share the findings of the evaluation such as ISDN meeting, stroke oversight and clinical lead meetings.

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Appendix

Abbreviations and Acronyms

AI	Artificial Intelligence	The simulation of human intelligence processes by machines, especially computer systems.
ASC	Acute Stroke Centre	Stroke centre that provides hyper acute and acute stroke care
CSC	Comprehensive Stroke Centre	Stroke centre that provides hyper acute and acute stroke care including thrombectomy
CT	Computerised Tomography	A CT scan uses X-ray measurements to produce cross-sectional images of body parts, in this case the brain
CTA	Computerised Tomography Angiogram	A CTA is a test that users X-rays to provide detailed images of the heart and blood vessels
CTP	Computer Tomography Perfusion	Perfusion scans involve injecting a small amount of radioactive substance into the body to show blood flow
DIDO	Door In Door Out (time)	Used to measure the time between a patient arriving at a stroke centre (ASC) and leaving after onward referral to a thrombectomy centre (CSC)
GIRFT	Getting in Right First Time	A national programme designed to improve the treatment of care of patients through in-depth review of services.
IMDRF	International Medical Device Regulators Forum	An international voluntary group of medical device regulators that aim to accelerate medical device regulatory harmonisation and governance.
INR	Interventional Neuroradiologist	Specialists that use radiological images to diagnose and treat diseases in a minimally invasive way.
ISDN	Integrated Stroke Delivery Network	Regional networks responsible for designing and delivery optimal stroke pathways.
IVT	Intra Venous Thrombolysis	Injection of a blood thinning agent, alteplase, which dissolves blood clots and restores blood flow.
LVO	Large Vessel Occlusion	The obstruction of large blood vessel in the brain, treatable by MT.
mRS	Modified Rankin Scale	A clinician reported measure of global disability that has been widely applied for evaluating recovery from stroke.
MT	Mechanical Thrombectomy	Involves removing a blood clot from the brain using a device, inserted through a catheter, to pull or suck out the clot and restore blood flow.
NOSIP	National Optimal Stroke Imaging Pathway	Evidence based pathway for acquiring brain scans for patients with suspected stroke
QALYs	Quality-adjusted life year	A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life.
SSNAP	Sentinel Stroke National Audit Programme	National healthcare quality improvement programme based at King's College London, measuring the quality of stroke care in the NHS and providing a single source of stroke data.

The limitations of the e-Stroke Real World Evaluation

Quantitative data limitations

Our primary source of quantitative data for the evaluation is from the long-established Sentinel Stroke National Audit Programme (SSNAP). This clinical component is a longitudinal register that collects a minimum data set of patient-level information about each stroke patient's clinical status and the care they receive from arrival at hospital, through their inpatient stay and community-based care, with follow-up 6 months after stroke onset. The quantitative data used in this evaluation was 'secondary', as it was derived from an extract of the SSNAP audit. As such, the data used was the best available to us, rather than including 'primary' data collection which would have been designed explicitly to fit the needs of the evaluation.
In addition:

- SSNAP data involves rigorous data quality control but there is always the possibility of errors in recording at individual sites.
- The SSNAP dataset may have been impacted by the COVID-19 pandemic, when clinical care was prioritised over local clinical audit with data collections being elective rather than mandatory. This may mean that in some cases important pathway metrics and patient outcomes are potentially under recorded.
- All NHS providers of acute inpatient stroke care are required to report to SSNAP's clinical database; however, community-based teams do not have this requirement and present data to SSNAP voluntarily. This has led to data, linked to rehabilitation, (for example the mRS score at 6 months) not being recorded in the patient record as consistently.
- The evaluation sites implemented e-Stroke at different time points, so it was not possible to directly compare outcomes over the same time period. We compensated for this by looking at data at all sites that was collected at least 12 months before the implementation of the technology.
- The metric that is derivable from SSNAP, "Time from first imaging to initial referral for intra-arterial intervention", would be the first choice in assessing whether e-Stroke could speed up decision making; however, this has only been captured in SSNAP since July 2021. All but four sites had implemented e-Stroke at this time, meaning we had no, or very limited, "pre-AI" data. We therefore had to compromise by looking at other metrics, for example, DIDO times (though DIDO is widely used in the NHS as a measure of performance in stroke pathways).
- There are many possible external confounding factors that could have impacted the outcomes that were observed during the evaluation. Some examples might include:
    - QI work on the stroke pathway in a particular stroke network.
    - Variation in experience of staff; for example, as clinicians gain more experience in the thrombectomy/stroke treatment pathway they may make relevant decisions quicker.
    - Variation in ambulance response times to 'transfer calls' (this will impact DIDO times, a better measure would have been to look at "Door In to decision to refer" as noted above).

Qualitative data limitations

- While our preference was to conduct 1:1 engagement with clinicians to explore their views and experiences of the technology, we had to consider other forms of gathering information, to reduce the research burden on clinicians who have often struggled to find the time to engage with our evaluation team.
- Eighteen months into the evaluation, during the Covid-19 pandemic, we adapted our methodology; We decided to use surveys which were designed to question key themes that were explored through the interviews. These included: set up and installation of the technology, clinicians' expectations, early impact on clinical outcomes, sharing of images, clinician satisfaction, early impacts on operational delivery, conditions for successful implementation and quality improvement. Surveys were left open for approximately 16 weeks to allow clinicians to provide feedback in their own time.
- This shift from in-depth interviews to surveys was also applied to our pathway mapping work, used to understand variation in the stroke pathway across sites and to assess the extent to which practices vary from the national standard, as set out by NICE. While we have relied on pathway-mapping interviews for baseline, we designed a survey for post-implementation data collection. Like the interviews, our pathway-mapping survey targeted operational and managerial roles, e.g. stroke project managers, stroke general managers and operational managers.
- This change in methodology was implemented due to the slow response rate we observed when trying to schedule 1:1 sessions, with clinicians. By September 2021, we had conduct 10 qualitative interviews over 8 sites and 24 pathway mapping interviews over 14 sites. However, 19 qualitative interviews were still outstanding alongside 16 pathway mapping interviews. Challenges to our interview schedule were caused by clinical and Covid-related pressures, particularly in the London Central & Northeast ISDN. Staffing pressures meant that clinicians had limited availability, which caused delays in getting some of the interviews organised, particularly across six sites: Eastbourne, Derriford, Queens Romford and three Bart's health sites. Moreover, some of the

interviews had to happen later than we would have anticipated due to three sites- Colchester, Southend, and Ipswich, being late sign-ups to the evaluation.

- Our schedule was also affected by installation delays, which slowed down engagement in the early phases of the evaluation. To overcome these challenges, we worked closely with Brainomix to coordinate activities around installation dates (plus 3 months usage, as all evaluation activities took place 3 months after the technology had been implemented). Despite these delays, fortunately all sites were fully installed by 30/09/21 which meant from that point on we had a full cohort that could contribute to the evaluation.
- Another issue that added a further layer of complexity limiting the scope of our engagement with sites has resulted from changes in staffing and reallocation of clinical leads. These developments have required us to establish relationships with new clinicians and to reschedule interviews several times. Our revised approach using surveys, has enabled clinicians to respond and provide feedback in their own time. This had a positive impact on our response rates. Providing a written questionnaire has also offered an added benefit; a higher level of accuracy in the information gathered. Written responses from clinicians have allowed our team to explore each statement in detail and to conduct complementary research when necessary to interpret the results. This can prove more challenging in the context of an interview when there is not always time to seek clarification before moving onto the next question.
- In addition to staff turnover-related challenges, throughout the evaluation there have been various changes at sites. These have been due to reconfigurations affecting different hospitals in our cohort. An example of this is the shift of acute stroke services from William Harvey and QEQM to the Invicta Ward at Kent and Canterbury Hospital, which has been providing acute stroke services for the whole of the East Kent region since April 2020. Basildon University Hospital and Broomfield Hospital were dropped from the evaluation and, Colchester General Hospital, Southend University Hospital and Ipswich Hospital were added. All new sites were onboarded with an interview to guarantee consistency in data collection methods and in the level of detail gathered across evaluation sites at baseline. It was crucial to ensure we could have face-to-face time with all sites at the start of the project as this allowed us to gain a deep understanding of all pathways and capture the nuances of each service. After this initial 1:1 engagement, sites with limited clinician availability were offered to complete a survey instead of a follow-up interview. Building a solid baseline helped us mitigate some of the risks that can emerge when diversifying data collection methods, notably inconsistencies in data accuracy and availability. Our questionnaire was carefully designed to ensure that all nuances captured through the interviews would be conveyed through a mixture of closed and open questions. 1:1 interviews provided the opportunity to seek clarification on certain aspects in greater depth. Switching to the use of a survey meant that we were unable to follow up or for example, understand more about why some of the pathway changes captured by our endline mapping survey have come about. This would have enabled us to contextualise some of our findings and draw more nuanced conclusions.
- Analysis of both pathway mapping and qualitative interviews and survey responses has been conducted through a qualitative analysis software which has enabled us to systematically code responses as they came through for thematic analysis. This systematic approach has allowed us to control for some of the data gaps mentioned above.
- Accuracy of the technology as a topic area would have benefitted from dedicated additional resources for the stroke physicians and radiologists, to compare their diagnoses results with that of Brainomix over the 3-year period at site. We compensated for this by comparing results from other studies conducted, along with our qualitative commentary provided by the clinicians over the 3-year period.

Appendix A - Link to full list of metrics considered.

Appendix B - Link to literature search on patient experience.

Appendix C - Link to Value Report

Appendix D - Link to Intervention Scalability Assessment