

AI in Health and Care Award

Evaluation Annual Report March 2023

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Background for the report

Around 100,000 people have a stroke in the UK every year with approximately 80% of people suffering a blockage in the brain which is called an ischaemic stroke. A third of these patients have a large vessel occlusion (LVO), which is a blockage in the neck or brain and this type of stroke contributes disproportionately to stroke-related dependence and death because of the potential to cut off blood supply to a large proportion of the brain. Around 12% of people admitted with acute stroke are eligible for thrombolysis (IVT), a clot busting drug which until recently was the only treatment for this type of stroke. IVT should be administered within 4.5 hours of onset of symptoms to achieve maximum benefit. More recently, mechanical thrombectomy (MT), which physically removes the clot from the vein has revolutionised stroke care and recovery, reducing brain damage and preventing or limiting long term disability.

The NHS long term plan in 2019 set out national targets for stroke care including increasing rates of MT from 1% to 10% by 2022. Early identification of LVO and quicker decision times can increase eligibility and therefore rates of MT. Identification of eligible patients is determined through brain scans, specifically CT, CTA and CTP imaging. However, there are few hospitals providing MT services.

e-Stroke by Brainomix is a CE-marked collection of tools that use AI algorithms to support doctors by providing real-time interpretation of brain scans to help guide treatment and transfer decisions for stroke patients, allowing more patients to get the right treatment, in the right place, at the right time, helping to expand patient access to life-saving stroke treatments by advancing the value of imaging.

This evaluation aims to understand if the inclusion of e-Stroke in existing stroke pathways can increase the number of eligible patients receiving IVT and MT by reducing the time required by clinicians to assess images and make treatment decisions and reducing the time to treatment because of improved communications.

I. Executive summary

What we looked at:

We have focussed predominantly on our effectiveness theme this period to determine;

- How clinicians feel about e-Stroke?
- If the introduction of e-Stroke has resulted in more patients getting the right treatment in the right place, within the recommended treatment window.
- If the introduction of e-Stroke has improved clinical, patient, experiential and operational outcomes?

What we found:

- 68% of clinicians are positive about e-Stroke and can identify many benefits and positive outcomes from its introduction into the acute stroke pathway.
- Thrombolysis rates have decreased across most sites, mirroring national rates.
- Clinicians believe that e-Stroke has led to the identification of more eligible patients for MT and that sites that use e-Stroke (limited to those participating in this evaluation) have a higher rate (4.21%) of MT than the national average (2.9%).
- The rate of MT is growing faster in ASCs in comparison to CSC which have also increased but remain consistent.
- Increased and consistent use of e-Stroke has a positive impact on DIDO times at ASCs, with sites adhering to the NOSIP recommendations and acquiring all available imaging at the same time seeing greater efficiencies.
- Clinicians attribute most value to decision support along with e-Stroke's ability to facilitate data and image sharing, as expediting the decision to transfer and accept patients for MT.

Given the richness of findings in this report, we have included links to key findings to assist navigation as follows:

- IVT rates and time to treat - [Page 11](#)
- MT rates – [Page 17](#)
- MT treatment and decision to treat times - [Page 27](#)
- Patient, clinical, experiential, and operational outcomes - [Page 35](#)

2. Introduction

2.1. Context of the evaluation

Early treatment with MT for patients who have an LVO is critical to rescue potentially salvageable tissue and reduce brain damage, preventing and limiting long term disability. Specialist radiological imaging: CT, CTA and CTP scanning is required to determine a patient's suitability for treatment, however, this, along with specialist teams are not available at all hospitals and referral to stroke units that can perform MT is a crucial part of the treatment pathway. AI driven imaging decision support software can positively contribute to the speed at which decisions are taken by clinicians when determining patients' suitability for treatment and transfer to their nearest thrombectomy centre.

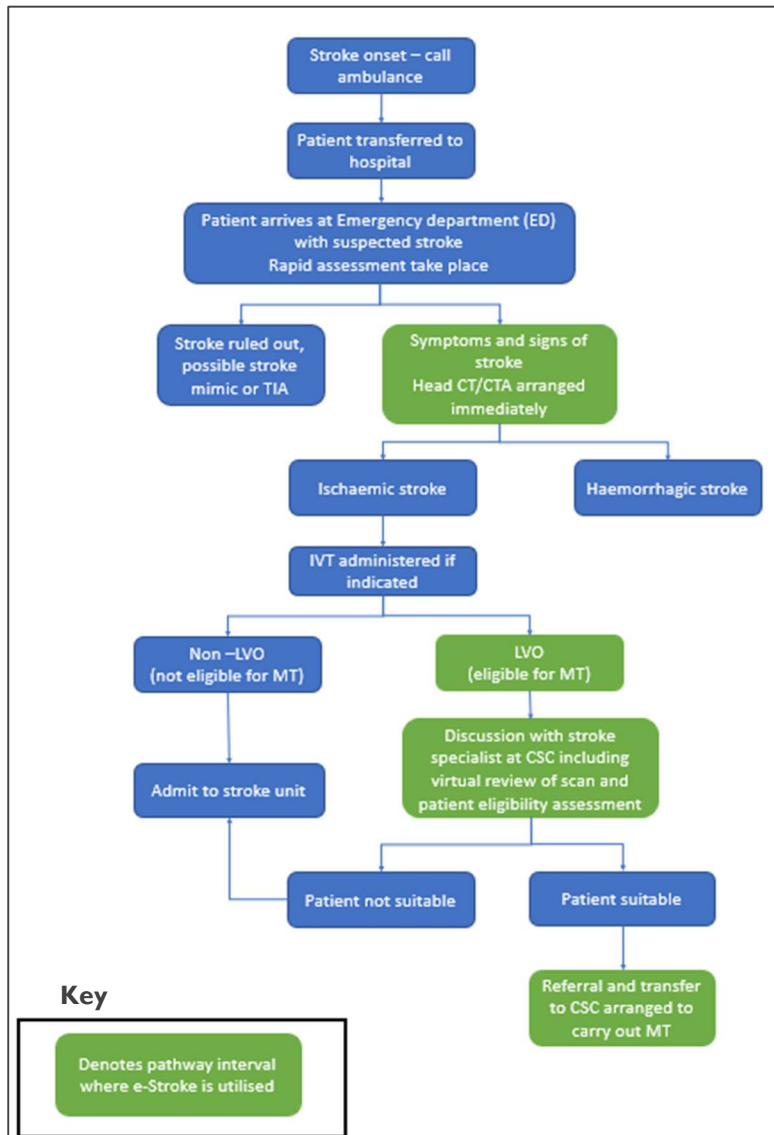


Figure 1: Simplified stroke pathway demonstrating utilisation of e-Stroke in an acute stroke centre setting

2.2. Evaluation questions and methodology

Hypothesis and evaluation questions

Despite this being a multi-year real-world evaluation, which relies on an iterative approach to adapt to a fast-changing stroke landscape which continuously sees new challenges and practices evolving, our hypothesis and value proposition have remained unvaried: “e-Stroke aids the evaluation 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”.

Our hypothesis relies on the assumption that the benefits of e-Stroke will be maximised through quality improvement initiatives. This is because clinical outcomes are likely to improve because of faster diagnosis and treatment which are being facilitated by the technology, but also because of improvements across the acute stroke pathway. We have now entered phase three of the evaluation. The closer we get to the end of the project, the more our efforts are being directed towards the identification of promising areas for quality improvement as our goal is to support the Integrated Stroke Delivery Networks (ISDNs) to optimize the benefits of e-Stroke, driving change and maximising impact on operational and clinical outcomes.

Our evaluation questions, which we agreed with our clinical stakeholders, are as follows:

- Does the technology produce the intended results? (Theme – Effectiveness)
- What are the outcomes for clinical, social, experiential and/or operational effectiveness? (Theme – Effectiveness)
- How accurate is the technology in a real-world deployment environment? (Theme – Accuracy)
- In a real-world setting, does the technology perform technically as described in a research setting? (Theme – Accuracy)
- What are the key risks and what assurance/management is in place? (Theme – Safety)
- Is each module of the technology compliant with the most appropriate reference standard for accuracy and safety? (Theme – Safety)
- What is the effect of the AI technology on current and future health and personal social care costs (Theme – Value)
- How do costs compare with health outcome benefits? (Theme – Value)

2.3. Methods overview

1. Design

This is a formative, mixed methods real world evaluation, running from January 2019 to March 2024 and comprises of the following elements:

- Review of the literature to establish the existing evidence on the effectiveness of reperfusion therapies for patients with ischaemic stroke to inform the development of our other evaluation topics.
- Qualitative analysis to establish the views of clinicians on the implementation, usability, accuracy, safety, and value of the technology.
- Quantitative analysis to assess the impact of the technology both in terms of effectiveness and value.
- Formative feedback to work collaboratively with clinicians and service leads to share progress, develop findings, and strengthen our interpretation of the evaluation.

2. Approach

Literature and evidence review.

We undertook a rapid, exploratory literature review to explore the characteristics of stroke and stroke services. The first literature review to place at the beginning of the evaluation period and aimed to provide a baseline of existing evidence and provide valuable insight into risk factors, treatment, patient outcome and measures, rehabilitation of patients following stroke, patient and carer experience, and associated costs of stroke to the NHS and social care. This work has guided our other approaches and has helped define our hypothesis.

Inevitably, during the lifespan of this evaluation, research in the treatment of patients with LVO and the development of AI technologies will continue, and new findings will be published, consequently our literature review continues to run in parallel to the evaluation and as a result will shape our findings, with a systematic literature review planned towards the end of this evaluation to support and validate our findings.

Qualitative analysis

Our qualitative analysis will inform two main streams of our evaluation. Firstly, through cross-case analysis, we are comparing commonalities and differences across sites to delineate the combination of factors that may contribute to clinical, patient, social and operational outcomes. This analysis will allow us to determine an

explanation as to 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 thus far comprise of:

- We analysed interviews with 18 clinicians which took place remotely during September 2021.
- We analysed 15 individual responses to our baseline survey and continue to analyse responses to our mid-term survey.
- We have mapped 17 acute stroke pathways, pre-implementation of e-Stroke and 11 post implementation of e-Stroke to determine variance and understand if the introduction of e-Stroke has led to efficiencies in the patient pathway. This work continues.
- Profiling hospitals based on static factors such as hospital type, patient volume, urbanicity and deprivation.

This approach has and will continue to assist in articulating our hypothesis and theories that emerge through the duration of the evaluation.

Secondly, these activities will also help us to understand the perceived impact and effectiveness of the technology and will take into consideration catalysts and barriers to implementation and sustained use and allow us to capture experiential feedback.

Quantitative analysis

We continue to receive clinical audit data via the Stroke Sentinel National Audit Programme (SSNAP) at a de-identified patient level. We have access to data from January 2019 and are receiving quarterly updates to this dataset. At the time of writing this report we were in receipt of data up to and including September 2022 and the analyses presented here are reflective of this period. We have used a pre-post test approach to our quantitative analysis, focussing on key intervals in the stroke delivery pathway to determine the impact of the technology to both clinical and operational outcomes. Outcome data from this source will also feed into and be used to confirm our cross-case analysis.

Formative feedback

As we have converged our analysis from both qualitative and quantitative sources, we have been able to share our progress and findings regularly with clinicians and other stakeholders to strengthen our evaluation approach and have taken 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.

Profiling

To support the development of recommendations to help sites make the best use of e-Stroke, we have developed site profiles based on a series of descriptive underlying factors. These factors include hospital type (hub vs. spoke), patient volume, site location, and local deprivation levels, and this will help us to understand which underlying factors are most likely to enhance or limit a site's ability to achieve its desired outcomes whilst creating appropriate benchmarking for future deployment. These profiles may evolve over time as more information and granular data becomes available.

3. Findings/Results

Our findings reflect our position at the end of year 2 of this 3-year evaluation. As a real-world evaluation, we have selected a quasi-experimental approach, using one group pre and post-test. Data presented in our findings is representative of 20 Acute Stroke Centres (ASC) or Spokes, and 6 Comprehensive Stroke Centres (CSC) or Hubs. These sites have been grouped into 5 evaluation ISDNs, reflective but not identical to their natural ISDN footprints.¹ The following findings are focussed on our 8 evaluation questions, addressing 4 main themes of Effectiveness, Value, Accuracy and Safety with 4 cross-cutting themes addressing Implementation, Feasibility, Fit for Site and Sustainability. We have developed a convergent, mixed method design to combine quantitative and qualitative data sources with data being collected simultaneously with various weights being assigned to the validity of the data source based on its availability and phase of the evaluation process.

NOTE

Due to data issues, the initial data analysis had to be repeated. The amendments have impacted some of our initial findings, for instance the number of thrombectomies increased, particularly at ASCs, and there was a knock-on effect on all MT related data (e.g. DIDO times; time from Scan to MT etc.). Data extract revisions resulted in additional data checking and subsequent re-analysis. The changes have led us to new insights which we are still in the process of working through. We are grateful to the SSNAP team for responding so quickly in addressing concerns that we raised about data quality and inaccuracies in the SSNAP data.

3.1. Does the technology produce the intended results? (Theme – Effectiveness)

To determine effectiveness, we have focused on the 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, thus enabling more people to undergo life changing treatment and procedures and ultimately reduce disability and improve quality of care.

To truly determine impact, we need to understand variances in local stroke pathways, in how different sites and professions utilise the technology and whether this is impaired by the level of skill and experience of staff. This analysis is then compared with clinical outcome data, in this case SSNAP.

We will first examine how rates of reperfusion therapies have changed over the period of the evaluation. 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 12.8% at the start of the data collection period in January 2019 to 10.9% in September 2022.

Thrombolysis % by Month Year



The observed trend mirrors the national thrombolysis rates according to the SSNAP publicly available dataset with the rates for the last quarter June-Sept 2022 being 10.8% nationally. We know from the SAMueL modelling and qualitative study¹ that 5 out of 10 patients who were treatable but did not receive IVT were because doctors chose not to proceed with treatment when other hospitals with higher rates of thrombolysis, would have done. Recent and ongoing clinical trials^{2,3,4} are attempting to test the current NICE guidance

¹ The TITaN network comprises of BOB ISDN and other sites in the East Midlands and West of England and was established as the Thames Valley Thrombectomy Innovation and Transformation Network. The London network includes to some but not all sites that are part of the London Supra Regional Network, specifically sites in Kent and East of England for the purposes of the evaluation.

NG128⁵ of IVT administered before or in parallel to MT. However, literature shows that those who have IVT before MT have equally good reperfusion rates as those who do not have thrombolysis⁶. In fact, IVT is thought to be beneficial for MT by enabling rapid dissolution of distal thrombi that develop during endovascular procedures, particularly in patients who present at ASCs who are then transferred to the regional CSC. Among the major reasons for not performing thrombolysis at referring hospitals were due to the stroke onset time not being determined when it potentially could have been which is further impeded by availability of CTP imaging at primary stroke centres.

Rates and time to treatment – all ASCs, pre and post implementation of e-Stroke.

	Pre implementation of e-Stroke				Post implementation of e-Stroke				Difference			
	Time in months	No of IVT patients	Rate of IVT	Median Scan to IVT	Time in months	No of IVT patients	Rate of IVT	Median Scan to IVT	Time in months	No of IVT patients	Rate of IVT	Median Scan to IVT
Colchester General Hospital	31	166	8.8	26.5	13	45	7.4	25	-18	-121	-1.4	-1.5
Dartford and Gravesham	20	67	9.6	37	24	95	9	38	4	28	-0.6	1
Eastbourne District General Hospital	28	111	6.1	43	16	87	8.7	48	-12	-24	2.6	5
Great Western Hospital	17	75	9.5	49	27	126	9.1	44.5	10	51	-0.4	-4.5
Invicta Ward Kent and Canterbury	18	0	0	0	25	268	14.9	30	7	268	14.9	30
Ipswich Hospital	31	168	11.8	41	13	53	11.1	47	-18	-115	-0.7	6
Maidstone	20	94	9.6	46.5	24	214	10.7	28	4	120	1.1	-18.5
Milton Keynes University Hospital	15	48	16.5	22	29	72	14.2	19	14	24	-2.3	-3
North Devon District Hospital	30	83	7.7	41	14	56	2.72	51	-16	-27	-4.98	10
Northampton General Hospital	18	132	9.1	27	26	166	8.6	28	8	34	-0.5	1
QEQM	18	68	12.1	30.5	25	5	11.1	50	7	-63	-1	19.5
Royal Berkshire Hospital	13	200	23.8	16.5	31	436	25.2	17	18	236	1.4	0.5
Royal Cornwall	26	169	8.8	38	18	74	5.6	47	-8	-95	-3.2	9
Royal Devon	24	165	9.8	31	20	134	9.9	32.5	-4	-31	0.1	1.5
Southend University	20	159	15.3	35	24	193	14.8	29	4	34	-0.5	-6
St Richards	27	130	12.7	35	17	100	14.8	36	-10	-30	2.1	1
Torbay	33	157	9.3	44	11	34	6.9	52.5	-22	-123	-2.4	8.5
William Harvey	18	94	12.7	41	25	10	3.4	56	7	-84	-9.3	15
Worthing Hospital	27	170	13.5	35	17	74	10.5	38	-10	-96	-3	3
Wycombe	17	135	12	25	27	245	14.2	33	10	110	2.2	8
Increased rates, decreased scan to IVT time	Decreased scan to IVT time, decreased rates				Increased scan to IVT time, increased rates				Increased scan to IVT time, decreased rates			

	Pre implementation of e-Stroke				Post implementation of e-Stroke				Difference			
	Time in months	No of IVT patients	Rate of IVT	Median Scan to IVT	Time in months	No of IVT patients	Rate of IVT	Median Scan to IVT	Time in months	No of IVT patients	Rate of IVT	Median Scan to IVT
Derriford	24	197	12.1	33	20	119	9.8	37	-4	-78	-2.3	4
John Radcliffe	18	149	15.3	31	26	315	20.7	21	8	166	5.4	-10
Queens Romford	30	403	14.4	22	14	112	11.1	25	-16	-291	-3.3	3
Royal Sussex	27	82	6.3	39.5	17	43	5.5	71	-10	-39	-0.8	31.5
The Royal London	25	371	17.3	15	19	184	12.9	23	-6	-187	-4.4	8
UCLH	32	388	10.9	16	12	123	11.4	18	-20	-265	0.5	2

Increase in IVT rates.	Decrease in IVT rates.	Increase in scan to IVT times.	Decrease in scan to IVT times.
Eastbourne Maidstone North Devon Royal Berkshire Royal Devon St Richards Wycombe John Radcliffe, UCHL	Colchester General Hospital Dartford and Gravesham Great Western Ipswich Milton Keynes Northampton Royal Cornwall Southend Torbay Worthing Derriford, Queens Romford, Royal Sussex, The Royal London	Dartford Eastbourne Ipswich North Devon Northampton Royal Berkshire Royal Cornwall Royal Devon St Richards Torbay Worthing Wycombe Derriford, Queens Romford, Royal Sussex, The Royal, UCHL	Colchester Great Western Maidstone Milton Keynes Southend John Radcliffe

From our qualitative analysis, evaluation sites have responded to suggest that e-Stroke does not have a significant impact on the decision time to administer thrombolysis, but over a third of those that responded to our survey do use e-Stroke to identify potential patients for IVT. It is important to understand how declining rates in thrombolysis have the potential to impact clinical and patient outcomes, and we have begun to explore this in the context of this evaluation on 'Patient outcomes based on treatment' (page 32).

We discussed why the rates of thrombolysis might be dropping with our evaluations sites during a formative feedback session in February 2023. Our hypothesis was that, as around 40% of patients in our evaluation are directly admitted to the CSC for MT, that they might progress directly with the MT procedure rather than waiting for the IVT to be administered, which can take over an hour. However, the graphs below shows that the rates of IVT appears to drop more substantially at CSCs in comparison to ASCs.

Rates of thrombolysis ASC average



Rates of thrombolysis CSC average



During the formative feedback session with key stakeholders, we determined that the main reason for not administering IVT is due to patients presenting outside of the treatment time (4.5 after onset of symptoms), or where the onset time is undetermined. It was also found that differences in workforce, such as having accessibility to stroke specialists to support the decision to administer IVT and clinical confidence are factors, with some ASCs discussing a patient's eligibility with teams at the CSC before proceeding with treatment.

Further analysis of data has shown that sites in the TITaN network appear to be increasing their IVT rates and in some cases speeding up the time of delivery. When we spoke with the stroke team in this network to understand how they have maintained and improved their IVT rates, we found that they spend time with the patient and relatives asking specific questions to determine the onset of stroke. It was also found that some of the hospitals in this region would administer IVT based on the patient's presentation and not the time from onset, so they would use their clinical expertise and experience to decide what was best treatment for the patient. Other stakeholders, in the Kent and Medway region, informed us that they consider age and frailty in their decision to administer IVT, with some sites deciding not to proceed if a patient has an mRS score of 3 or more. We will perform further analysis, standardising age and frailty to determine whether this is a factor in the rates dropping.

It is clear that practice differs across sites and ISDNs, with TITaN having the most consistently improving rates shown below, in comparison to SouthWest Peninsula, where rates are significantly lower and also decreasing.



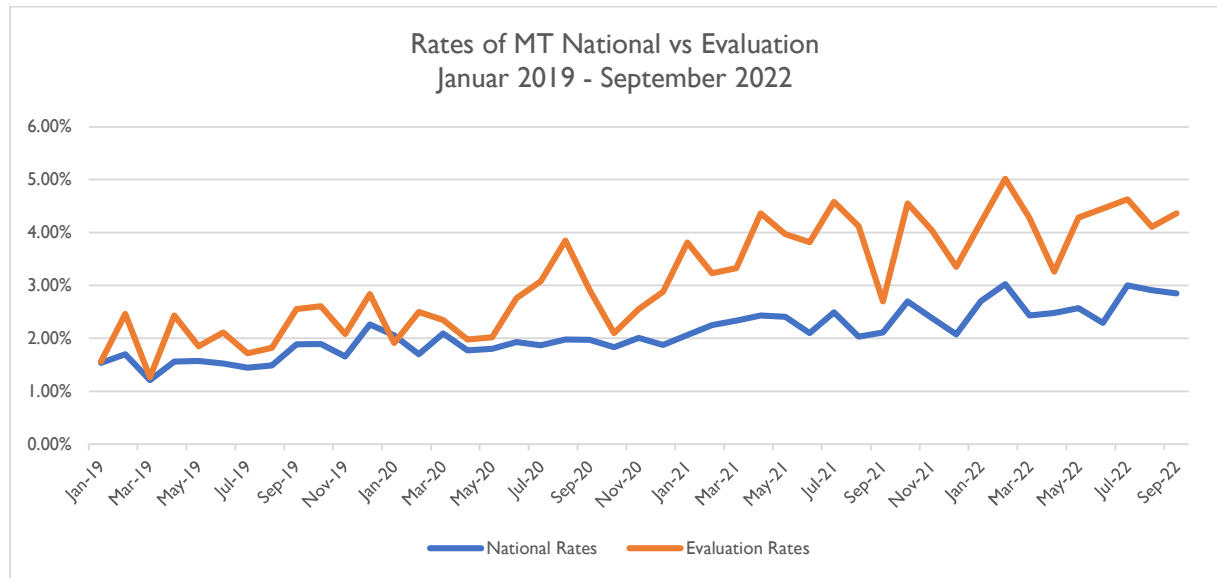
From a CSC perspective, stakeholders from London told us that if a patient is directly admitted to the CSC for treatment and their ASPECTS score is good, then the patient is prioritised directly for MT, this practice may account for the decreasing rates across the London ISDN as this region has more CSCs than any other in the country. The general advice across CSCs when accepting a patient for MT, would be to administer IVT and get the patients transferred as soon as possible, however, teams working at CSCs noted there were often significant delays in this part of the pathway when images were not being acquired at the same time. An example of this would be where a patient has a plain CT scan at an ASC, the images are transferred to CSC via e-Stroke and the patient is discussed, however a decision cannot be reached without a CTA scan, this then has to be carried out before the patient's eligibility for transfer can be confirmed. This delay can take up to an hour, all the while the patients' eligibility for both IVT and MT is diminishing.

Key points

- We can determine that the decrease in IVT rates is due to factors such as transfer times from home to hospital meaning the treatment window has passed, or 'last time known well' is not recorded or not known.
- The administering of IVT is reliant on the skills and expertise of the stroke unit when a patient is admitted, and this differs from site to site. In some cases, the ASC teams will ask for decision support from the regional CSCs before they proceed with IVT.
- e-Stroke has the potential to improve rates of thrombolysis, particularly when using the e-ASPECTS module. Further training and support for ASCs on how to use this part of the software is recommended.
- Adherence to the NOSIP is key, if ASCs can acquire CT and CTA images at the same time and use e-Stroke to support their decision making, the rates of thrombolysis should increase.

Rates of MT

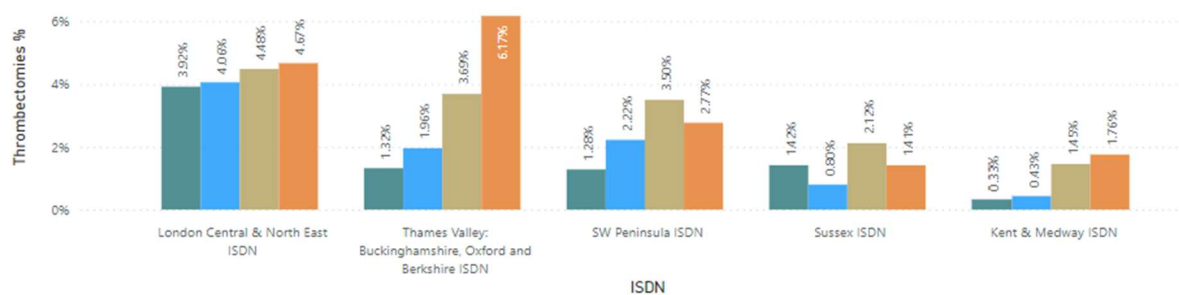
The NHS Long Term Plan and Getting it Right First Time (GIRFT) programme, also committed stroke services in England to increasing rates of MT from 1% to 10% by 2022. Our analysis has shown that whilst rates of MT vary across evaluation sites, they continue to increase despite the impact of Covid. The evaluation average has risen from 1.5% to 4.2% from January 2019 to September 2022 with some evaluation sites achieving rates more than 8%. 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.



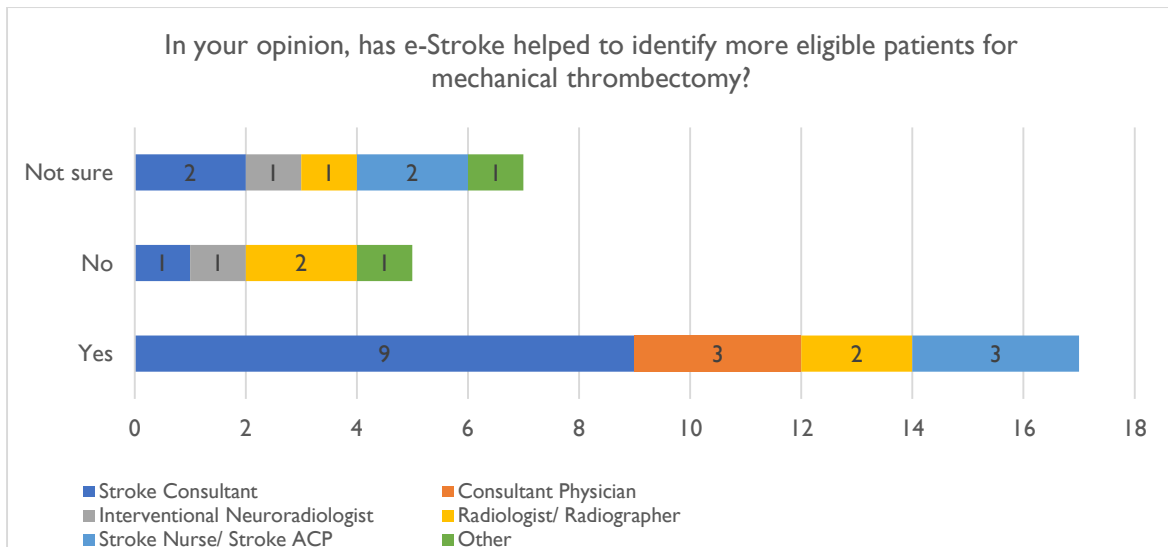
As expected, across all 5 participating ISDNs, considering that the final year is only 6 months of data, the rates of mechanical thrombectomy are increasing over time. This in part is due to many factors such as the impact of national targets, increased skill sets, availability of mechanical thrombectomy services and the establishment of the Integrated Stroke Delivery Networks. Our evaluation will determine to what extent the introduction of e-Stroke has impacted on mechanical thrombectomy rates, through earlier identification of eligible patients and speeding up the decision to treat.

Thrombectomies % by ISDN and Year

Year ● 2019 ● 2020 ● 2021 ● 2022

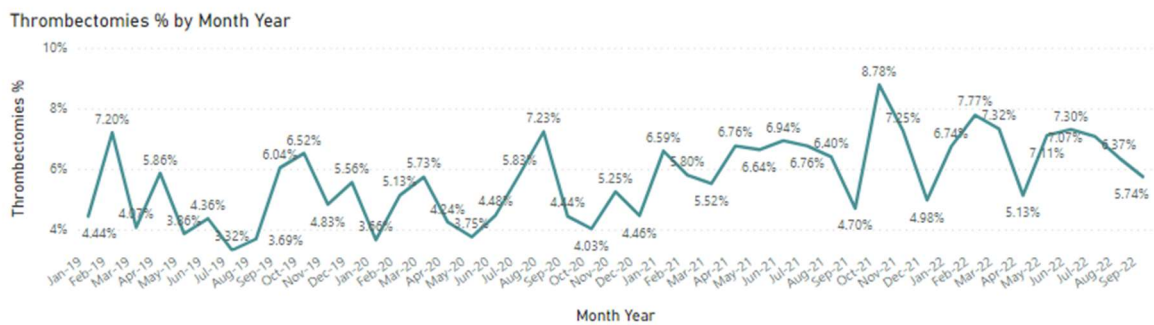


When asked in our mid-term survey if e-Stroke has helped to identify more eligible patients for MT, of the 29 people that responded, 18 (62%) believed that e-Stroke did help, a further 7 (24.1%) weren't sure and 5 (17.2%) thought that it did not help.



It seems from this response that clinicians who have specific expertise in either carrying out MT (Interventional Radiologist) or those that interpret brain scans (Radiologists) see less value in e-Stroke identifying more suitable patients, whereas Stroke Consultants, Physicians and Specialist Stroke Nurses and Practitioners, see greater value. This would indicate that clinicians that already have the necessary skills and expertise to treat MT are less reliant on the software, further corroborated by the type of hospital that the clinicians are based, with 16, or 89% of clinicians in ASCs responding that it does help (of the 5 people that disagreed, 2 were CSC (40%) and 3 were ASC (60%). Of the 18 that agreed, 16 were ASC (89%) and 2 were CSC (11%). This is also reflected in the rates of MT at CSCs compared to ASCs, with ASC improved MT rates consistently over time, the CSCs are more consistent. It is clear that the introduction of e-Stroke at ASCs have increased the number of eligible patients undergoing MT.

Rate of MT – all CSCs



Rate of MT – all ASCs



Increasing rates outside the treatment window

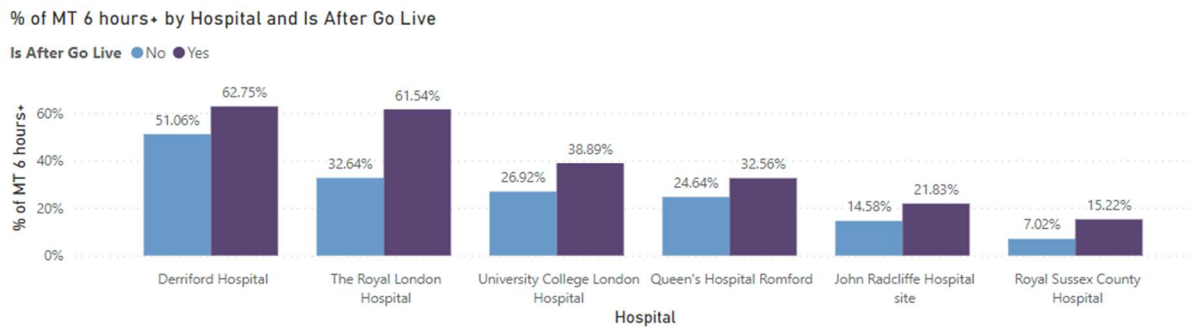
To further investigate if e-Stroke is increasing the number of eligible patients receiving MT and if the decision to refer patients for MT is speeding up, it is important to consider the treatment window. It is well researched and recommended by NICE that the 6-hour window is crucial when delivering MT^{3,7,8,9} as it ensures

better outcomes for the patient, functionality etc. This analysis will also help us to determine the potential for change.

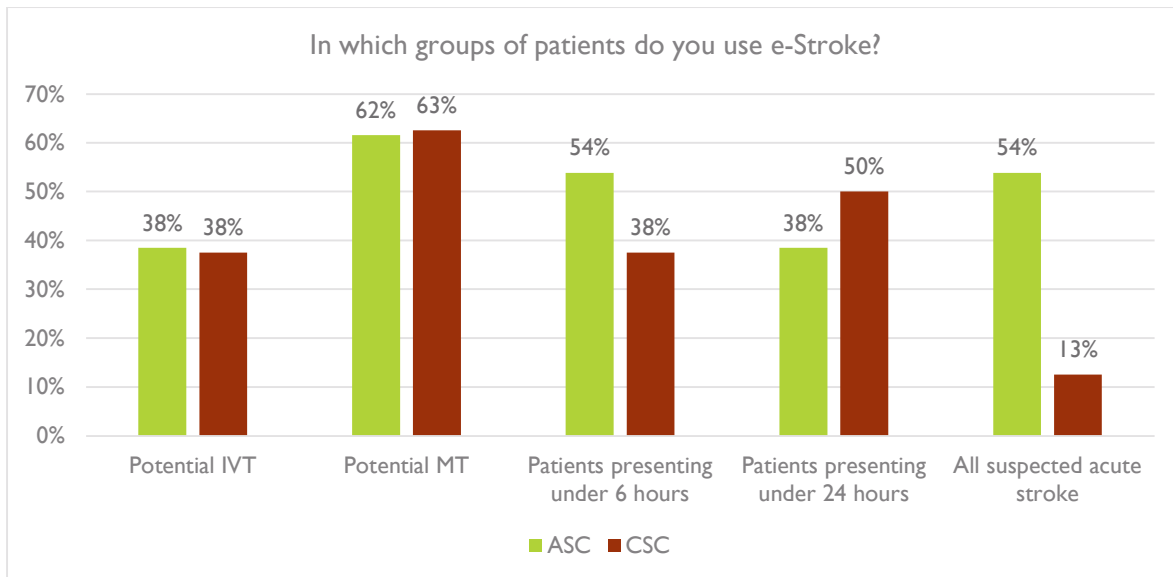
The graph below shows the number of MT being carried out in excess of 6 hours is increasing over time across our evaluation sites. The use of MRI and CTP has allowed for expansion of the treatment window for MT to 24 hours from the time last know well. Given that all CSCs have access to CTP advanced imaging, the number of patients now eligible for MT is significantly larger, which is reflected in the increase in rates. (REF)



We can also see that since the adoption of e-Stroke in our CSCs, the percentage of patients undergoing MT more than 6 hours after onset of symptoms is increasing.



We know from our mid-term survey that e-Stroke is used across evaluation sites for patients that present less than 24 hours after onset of symptoms. The graph below depicts this by those that work at ASCs and CSCs and whether their use case is different.

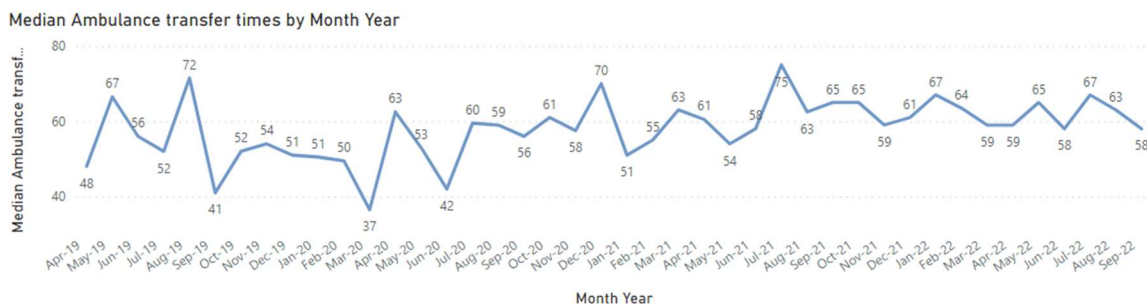


(Data taken from mid-term survey. 26 individual responses from ASCs and 8 individual responses from CSCs).

This graph shows that whilst staff at ASC and CSCs use e-stroke comparably for patients who would be potential candidates for IVT and MT, staff working at CSCs would use e-Stroke more for patients presenting within 24 hours of onset of symptoms. This may be in part due to the accessibility of CTP scanning in CSCs, as only 3 ASCs in our evaluation have access to this type of scanning which can confirm a patient’s eligibility for MT up to 24 hours. However, it is also a likely outcome of e-Stroke’s rapid image sharing functionality, meaning that ASC teams have more immediate access to thrombectomy specialists who would accept patients based on their expertise and knowledge. Before the implementation of e-Stroke, it would be more likely to decline a patient for transfer if they were last known well more than 6 hours ago as they did not have any further information (brain scans) available to them to inform this decision. This argument is further supported by ASCs using e-Stroke for all suspected acute stroke (both ischaemic and haemorrhagic), suggesting that they rely more on the software supporting their general decision making as the neurology expertise isn’t always available.

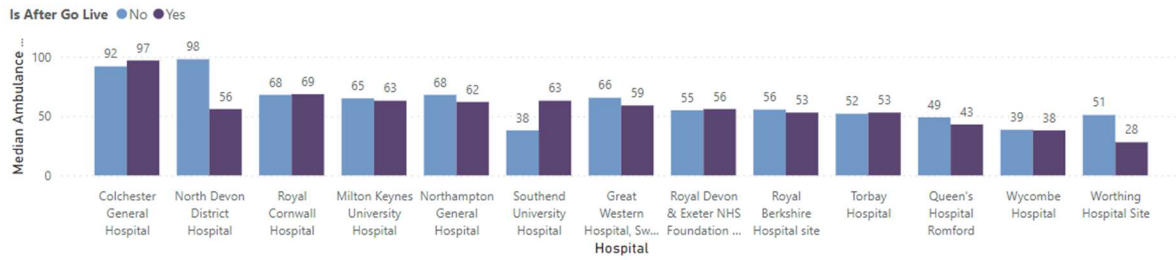
Transfer from ASC to CSC

When considering time to referral and treatment, it is important that we consider transfer times between sites. We are aware from our qualitative analysis, that ambulance transfer times from ASCs to CSCs are a limiting factor in the delivery of MT, particularly across the Southwest Peninsula. The graph below shows median ambulance transfer times from ACS to CSC over time. This suggests that transfers times have increased slightly over the period of the evaluation, but little can be reasonably deduced from this in isolation.



We are also able to determine which of the ASCs in the evaluation are most effected by ambulance transfer times in the graph below and if this has become more of a limiting factor post implementation of AI.

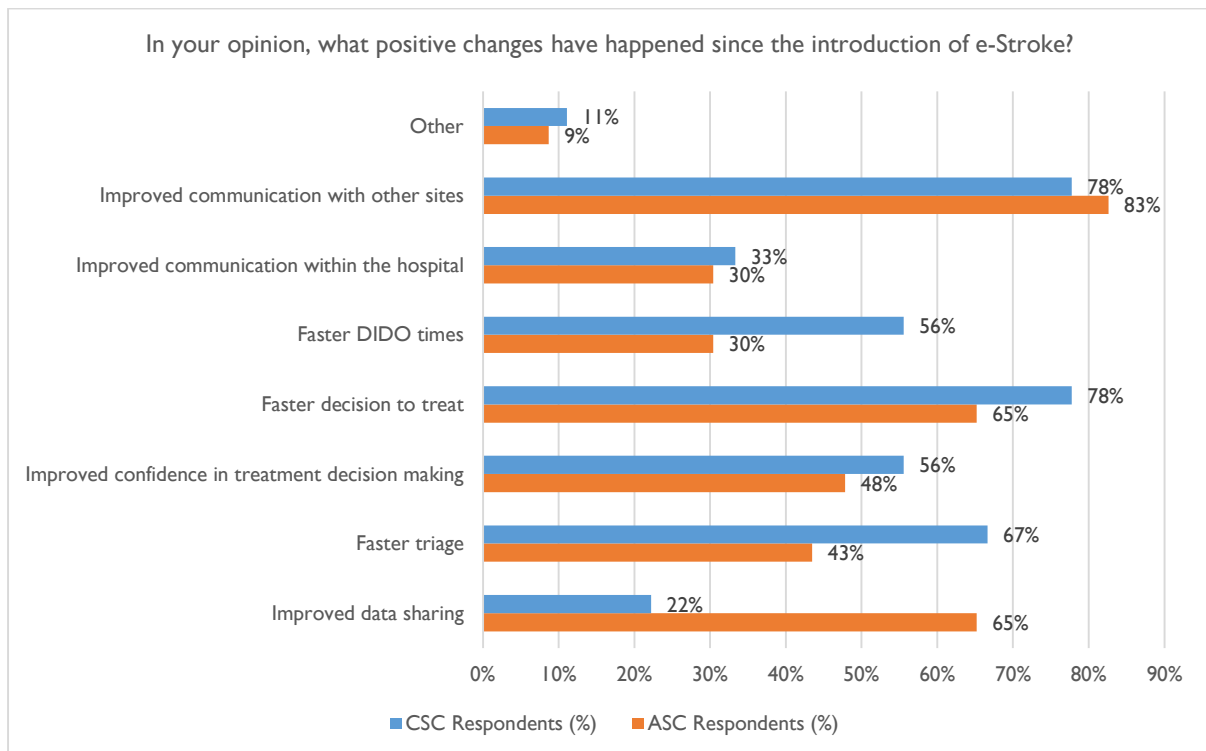
Median Ambulance transfer times by Hospital and Is After Go Live



Only sites which have sufficient ambulance transfer data for MTs have been included.

Of interest, Colchester Hospital has amongst the lowest MT rates across all evaluation sites which are declining over time. It may be that the length of the transfer time to the CSC for this site is a factor when transferring and accepting potential candidates for MT. We know that, despite having a CSC in their ISDN (Norfolk and Norwich University Hospitals (NNUH)), this site refers almost exclusively to the London network after becoming part of the connected region in 2021. A rudimentary check on google maps would suggest that both NNUH and the sites in London are around the same distance, so this would suggest that this site, and others in the same vicinity such as Ipswich Hospital and their relative patient populations, may benefit from a CSC closer to home or the availability of the air ambulance to facilitate quicker transfer times for treatment. Comparatively, Wycombe has one of the highest rates of MT for ASC and consistently has the lowest transfer times to the CSC.

These metrics are relatively new to our evaluation, and it would be valuable to do further analysis, however, based on what we see here, the transfer time does not appear to be as much of a limiting factor as we first suspected. Upon investigating this further with colleagues from TITaN ISDN, the biggest impact on the transfer of patients to a thrombectomy centre is the time it takes to obtain an ambulance at the ASC, which is included and therefore detrimental to the in the Door in Door Out (DIDO) time of individual patients.



As this is a multiple-choice question, percentage respondents are calculated by dividing each answer by the total unique respondents, therefore the total does not add up to 100%.

The responses to this question, confirm our theories that although ASCs and CSCs stand to benefit in different ways from the introduction of e-Stroke, they do consider the same factors that have led to positive

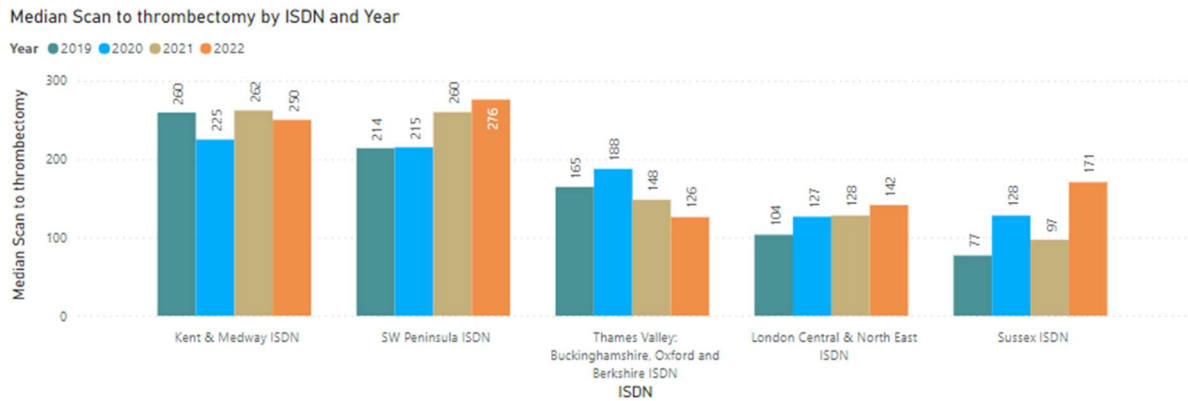
outcomes in their acute stroke pathways. Overwhelmingly the positive changes that have happened since the introduction of e-Stroke are improved data sharing and communication with other sites, which are both functions of the software that sit alongside its AI decision support. These have both been confirmed by the increased rates of MT in our evaluation sites compared to the national average.

Key points

- The technology has improved communication within stroke teams, both locally (hospital site), and regional (ISDN).
- The technology is used differently depending on profession and whether at an ASC and CSC. At ASC e-Stroke is used in more generalised acute stroke cases and as a mechanism to gain support from more experienced colleagues, who may be on call, working at another site or, at a CSC, on treatment decisions for patients.
- The use of e-Stroke is facilitating the expansion of the treatment window for MT up to 24 hours from time last known well.
- e-Stroke has the potential to further improve rates of mechanical thrombectomy, particularly when the patient pathway is optimised.

Decision to treat.

We will now observe the key intervals in the acute stroke pathway that stand to be impacted by the introduction of e-Stroke. At an evaluation level the time from scan to MT is increasingly slightly, however this varies significantly across our ISDNs.



Of the 30 people asked, 25 (83%) said that the introduction of e-Stroke had reduced the time taken to reach a decision to proceed with MT. Of this, 100% (6/6) CSC staff agreed and 73% (19/26) agreed.

However, as the time from scan to MT houses many smaller intervals of the stroke pathway and is impacted by access to the CSC for thrombectomy and distance to the CSC, including ambulance waiting and transfer times, we have focussed more specifically on two key pathway intervals that are impacted by the introduction of e-Stroke.

We know from Holodinsky et al¹⁰, that achieving a door in door out (DIDO) time of less than 60 minutes at an ACS can ensure a patient has similar benefits and outcomes as they would if they were received primarily by the CSC. For the ASCs where we have sufficient data from SSNAP, we have analysed DIDO time pre and post implementation of e-Stroke. To appreciate the speed of MT delivery at CSC, we have also looked at time from scan to mechanical thrombectomy pre and post implementation of e-Stroke.

Rates of MT and DIDO times all ASCs – pre and post implementation of e-Stroke

	Pre implementation of e-Stroke				Post implementation of e-Stroke				Difference			
	Time in months	No. MT patients	Rate of MT	Median DIDO	Time in months	No. MT patients	Rate of MT	Median DIDO	Time in months	No. MT patients	Rate of MT	Median DIDO
Colchester General Hospital	31	20	1.06	169.5	13	10	1.63	189.5	-18	-10	0.57	20
Dartford and Gravesham*	20	2	0.29	132.5	24	24	2.26	159	4	22	1.97	26.5
East Kent University Hospitals	18	5	0.27	185	25	70	3.73	123	7	65	3.46	-62
Great Western Hospital	17	9	1.14	158	27	35	2.53	224	10	26	1.39	66
Maidstone	20	3	0.31	121	24	24	1.2	143	4	21	0.89	22
Milton Keynes University Hospital	15	3	1.03	93	29	25	4.93	92	14	22	3.9	-1
North Devon District Hospital	30	13	1.21	150	14	12	2.72	302	-16	-1	1.51	152
Northampton General Hospital	18	6	0.41	115.5	26	36	1.87	165	8	30	1.46	49.5
Royal Berkshire Hospital	13	11	1.31	151	31	62	3.58	90	18	51	2.27	-61
Royal Cornwall	26	17	0.88	140	18	31	2.34	174	-8	14	1.46	34
Royal Devon	24	26	1.54	121.5	20	49	3.62	192	-4	23	2.08	70.5
Southend University	20	10	0.97	239	24	33	2.53	200	4	23	1.56	-39
St Richards	27	5	0.49	190	17	10	1.48	131.5	-10	5	0.99	-58.5
Torbay	33	24	1.43	183.5	11	5	1.02	136	-22	-19	-0.41	-47.5
Worthing Hospital	27	15	1.19	110	17	8	1.13	138	-10	-7	-0.06	28
Wycombe	17	23	2.04	90	27	78	4.53	90	10	55	2.49	0

Sites not included: Eastbourne (3 MT post implementation, zero before); Newham (2 MT pre implementation, zero after); Ipswich (10 patients pre implementation, zero after)

East Kent University Hospitals represents Invicta, QEQM and William Harvey.

*NB DIDO has increased as only 2 MT pre implementation, however DIDO post-implementation is reducing.

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

<p>Increase in MT rates.</p> <p>Colchester Dartford and Gravesham East Kent Hospitals Great Western Hospitals Maidstone Milton Keynes North Devon Northampton Royal Berkshire Royal Cornwall Royal Devon Southend St Richards Wycombe</p>	<p>Decrease in MT rates.</p> <p>Ipswich (no MT post implementation) Torbay Worthing (only 0.06% decrease)</p>
<p>Increase in DIDO times.</p> <p>Colchester Dartford and Gravesham Great Western Maidstone North Devon Northampton Royal Cornwall Royal Devon Worthing</p>	<p>Decrease in DIDO times.</p> <p>East Kent Milton Keynes Royal Berkshire Southend St Richards Torbay Wycombe (stayed the same)</p>

Interestingly, there are a minority of sites that have increased their DIDO times but decreased the Scan to IVT times and vice versa. These time periods require further investigation with the individual sites to better understand the factors impacting these pathway intervals, for example, does this show that the stroke unit processes are improving but the limiting factor is the availability of ambulances for transfer? To this end, we have requested further detail from SSNAP to quantify the pathway intervals precisely.

To determine if the snapshot demonstrated in the table above is a sustained trend, we plotted individual patients DIDO times using scatterplots. DIDO time (in minutes) for individual patients was plotted on the y-axis and date of event (month/year) on the x-axis for each individual patient. Data points and trendlines, pre and post-implementation of e-Stroke, has been indicated chromatically. We applied t-test methodology to the residuals to identify outliers which have been removed from these charts. Number of patients included and excluded both post and pre implementation are indicated in the figure legends.

Of the 20 Acute Stroke Centres participating in our evaluation, we have sufficient data on patients transferred for mechanical thrombectomy for 16 ASCs to enable a time trend DIDO analysis.

Of those 16 sites, 11 sites DIDO times were getting longer over time pre-implementation of e-Stroke. 2 sites had consistent DIDO times and 3 sites seemed to be reducing their DIDO time.

Post implementation of e-Stroke **8 sites decreased** following implementation, with **4 sites continuing to reduce or sustain DIDO over time** (St Richards, Torbay, RBH and East Kent). 4 have shown an increase to their DIDO over time (North Devon, Royal Cornwall, Royal Devon and Exeter and Worthing).

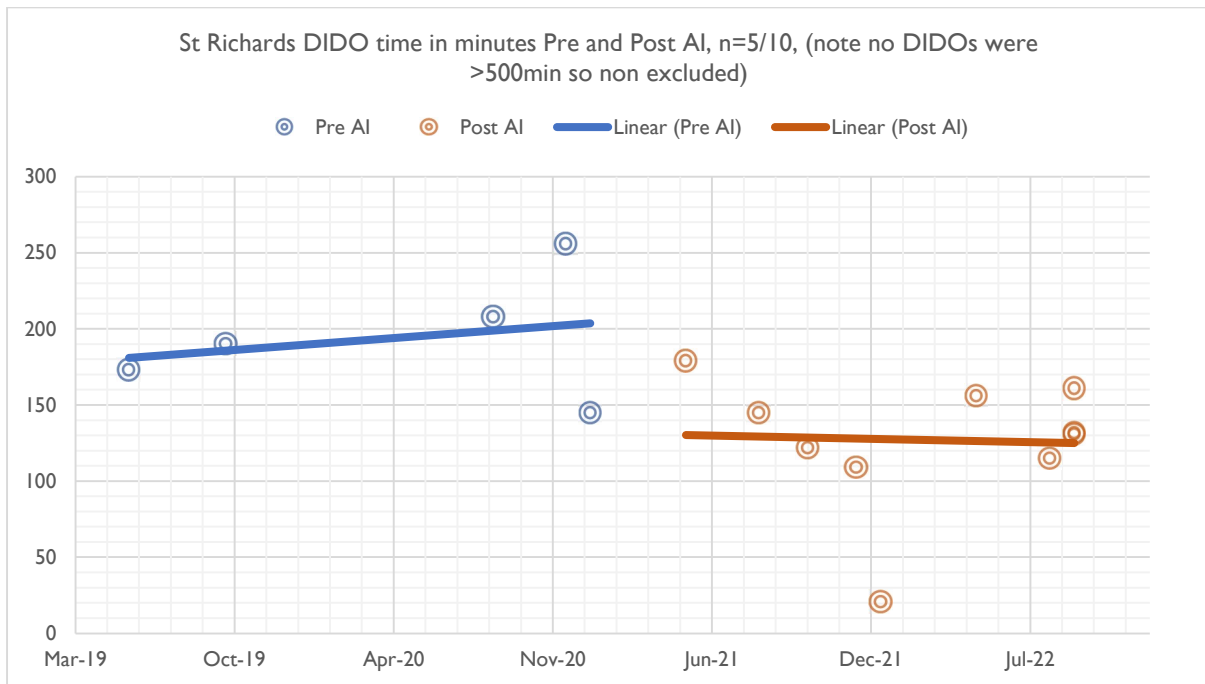
3 sites had no significant impact on implementation but have decreased DIDO over time (Wycombe, Milton Keynes and Darent Valley)

2 sites showed no significant impact (Colchester and Southend)

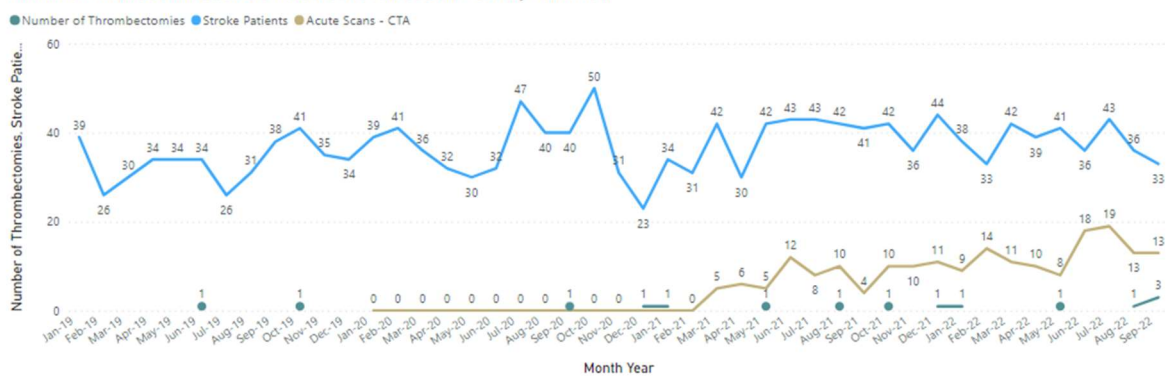
4 sites have shown an increase to their DIDO times (Great Western, Northampton, Maidstone and Colchester).

Below we have compared for a selection of the sites, the trends in DIDO times alongside usage data. In these examples, we have chosen to present the number of CTA scans that are processed by e-Stroke in each site. We have chosen this modality as CTA scans are available across all sites and are used to determine a patient's eligibility for mechanical thrombectomy.

St Richards – Sussex ISDN

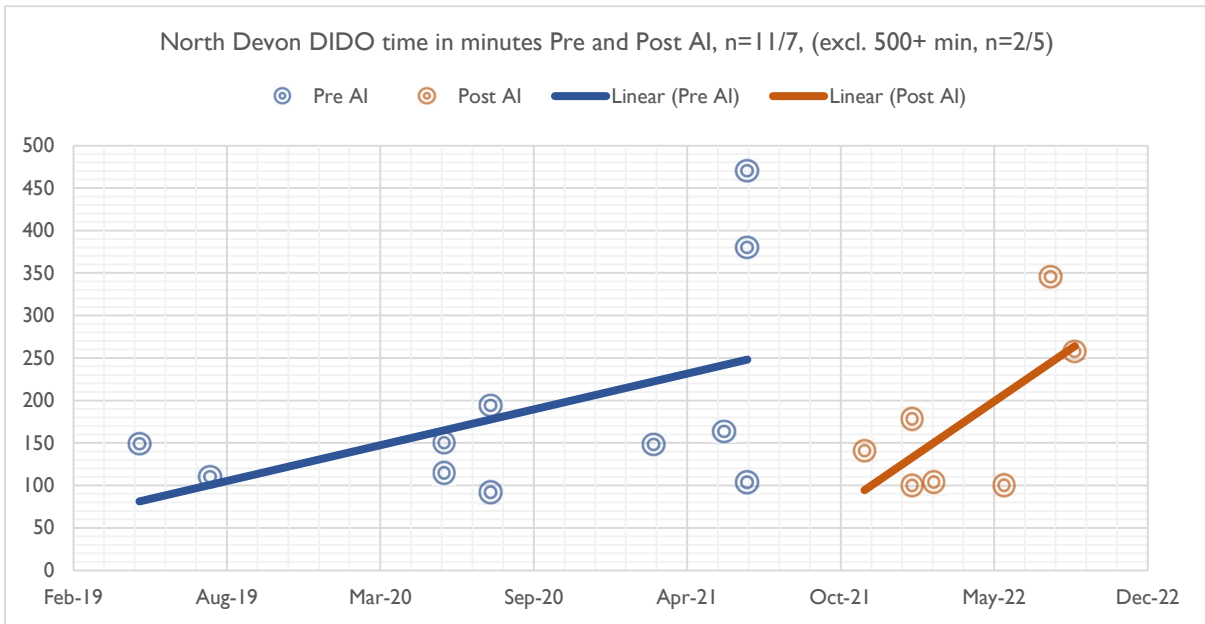


Number of Thrombectomies, Stroke Patients and Acute Scans - CTA by Month Year

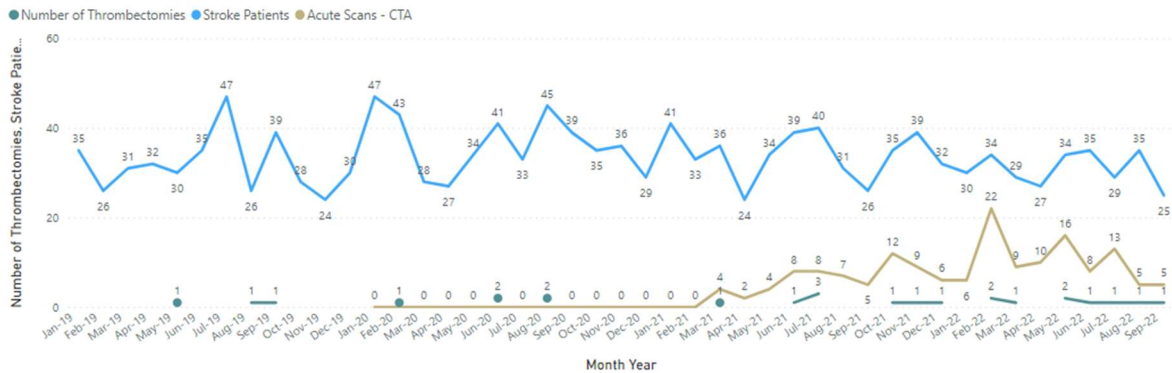


We know from our mid-term survey that the team at St Richards use e-Stroke for more than half of cases and this is reflected in the usage data. The number of CTA scans is increasing at this site. We can assume that e-Stroke is facilitating quicker DIDO times at this site.

North Devon – Southwest Peninsula ISDN

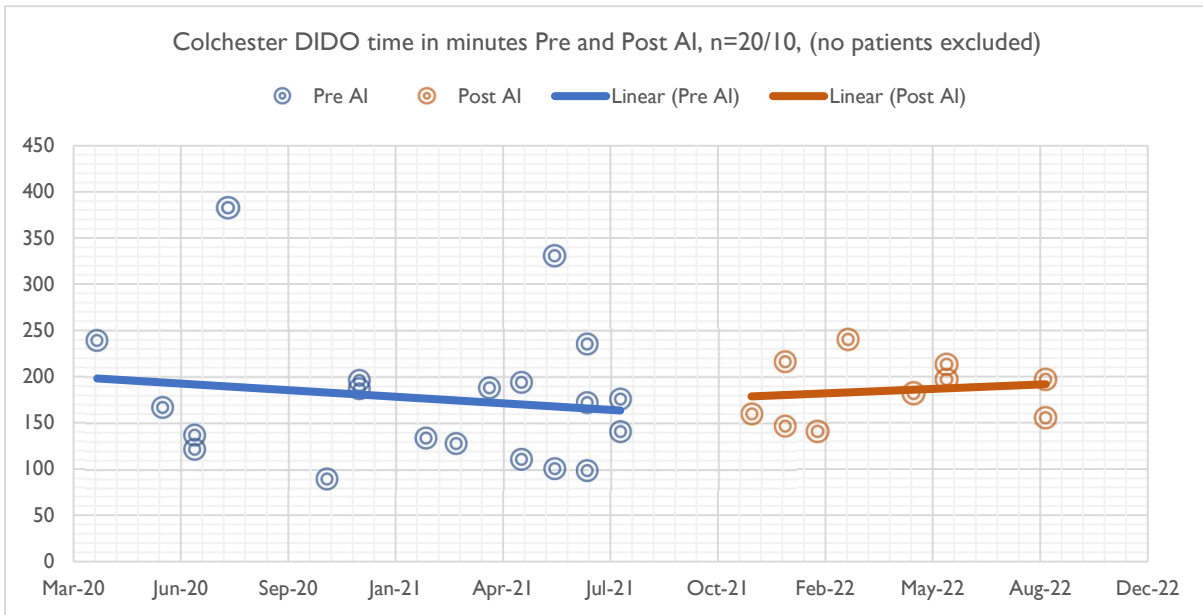


Number of Thrombectomies, Stroke Patients and Acute Scans - CTA by Month Year

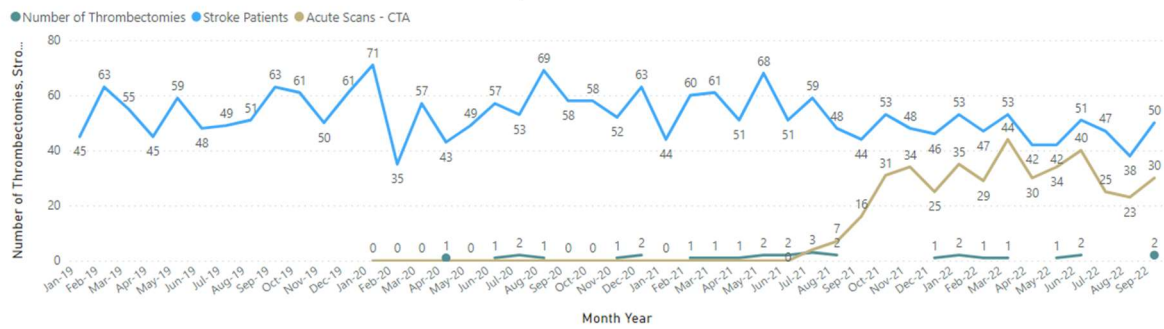


Usage data at this site peaks between October 21 and May 22 where the DIDO times are low, as usage of the technology tails off, DIDO times increase. We can assume that when the technology is used in this site, it is facilitating quicker DIDO times. We have not had any survey responses from this site to confirm this hypothesis, so this does warrant further investigation.

Colchester – London ISDN (part of the Supra Regional London network)

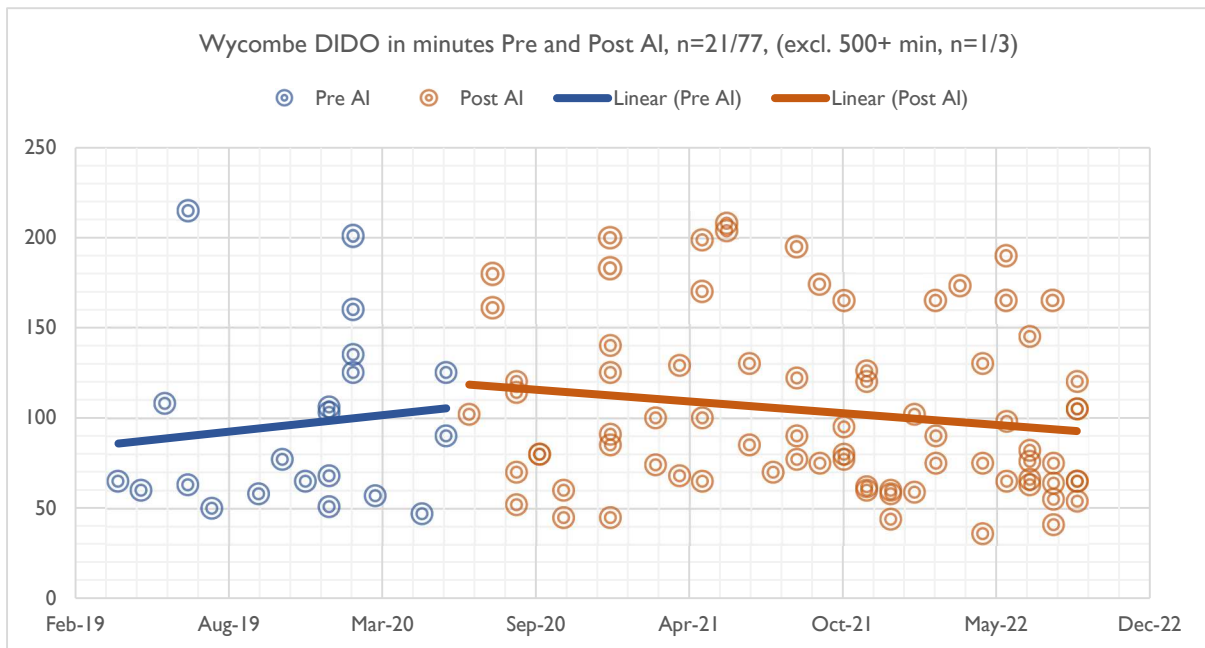


Number of Thrombectomies, Stroke Patients and Acute Scans - CTA by Month Year

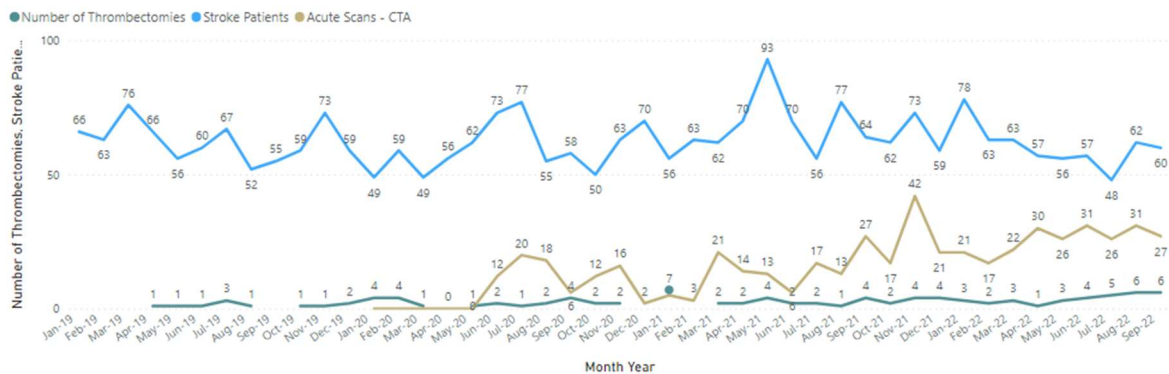


Implementation of e-Stroke in this site appears to have made DIDO times more consistent. This is mirrored by usage, which also remains consistent particularly in comparison to the number of stroke admissions. We know that clinicians working at this site use the technology in different ways, some to determine eligibility for thrombolysis but all use it to determine eligibility for MT. All staff are either satisfied or very satisfied with the capabilities of e-Stroke.

Wycombe – TITaN ISDN



Number of Thrombectomies, Stroke Patients and Acute Scans - CTA by Month Year



We are aware that this hospital has carried out DIDO audits and have as a result, implemented a variety of quality improvement measures, with significant improvements made through automatic triggering of CTA scans in thrombectomy candidates. This is reflected in the e-Stroke usage data which shows a steady increase in the number of CTA scans processed by the technology.

We can assume, that the increased use of technology, alongside quality improvement activities, has facilitated the reduction in DIDO times for this site.

CSC Scan to MT times

	Pre implementation of e-Stroke				Post implementation of e-Stroke				Difference			
	Time in months	No of MT	Rate of MT	Median Scan to MT	Time in months	No of MT	Rate of MT	Median Scan to MT	Time in months	No of MT	Rate of MT	Median Scan to MT
Derriford	24	63	3.87	171	20	65	5.37	173	-4	2	1.5	2
John Radcliffe	18	19	1.95	73	26	129	8.46	63	8	110	6.51	-10
Queens Romford	30	115	4.14	107	14	56	5.56	112	-16	-59	1.42	5
Royal Sussex	27	40	3.07	67	17	37	4.7	82	-10	-3	1.63	15
The Royal London	25	155	7.25	96	19	95	6.66	117	-6	-60	-0.59	21
University College London	32	147	4.16	102	12	69	6.42	98	-20	-78	2.26	-4

This table only looks at patients that were directly admitted to the CSC.

Of the 6 CSCs participating in this evaluation, 3 sites scan to MT times were getting longer over time pre-implementation of e-Stroke. 2 sites had consistent scan to MT times and 1 site seemed to be reducing their scan to MT time.

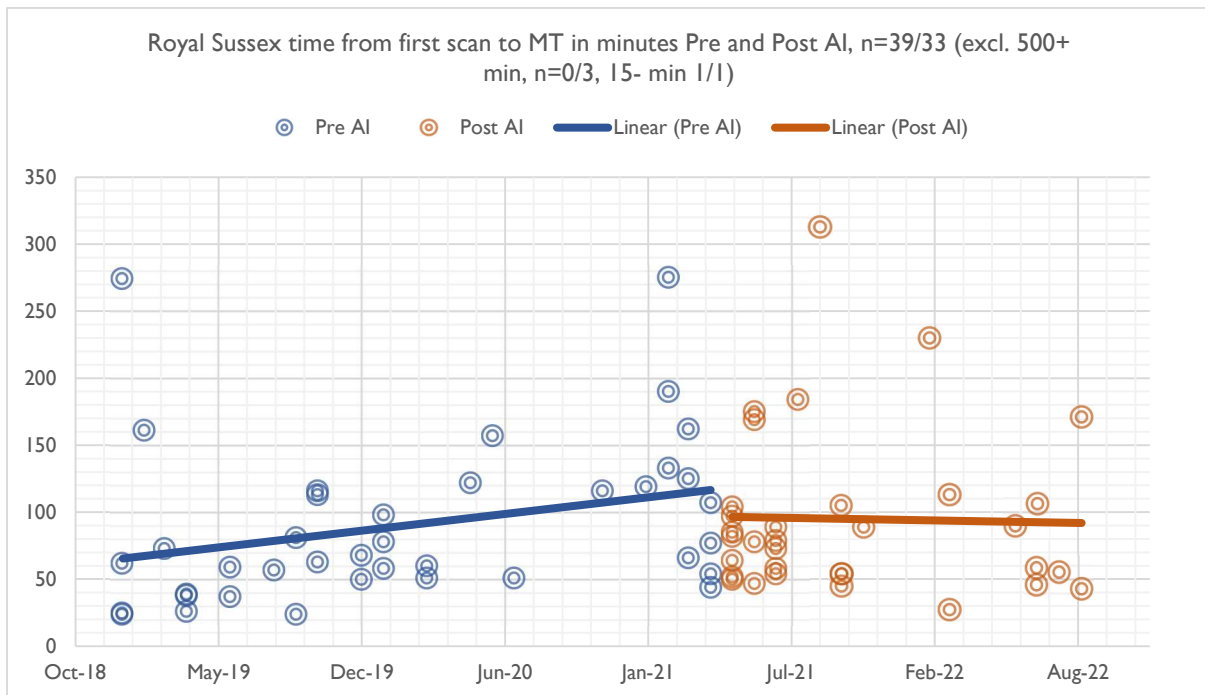
3 sites decreased following implementation, with **1 site continuing to reduce scan to MT time** (Sussex). 2 have shown an increase to their scan to MT over time (The Royal London and Derriford Plymouth).

2 sites had no significant impact on implementation but have decreased scan to MT over time (Queens Romford and John Radcliffe Oxford)

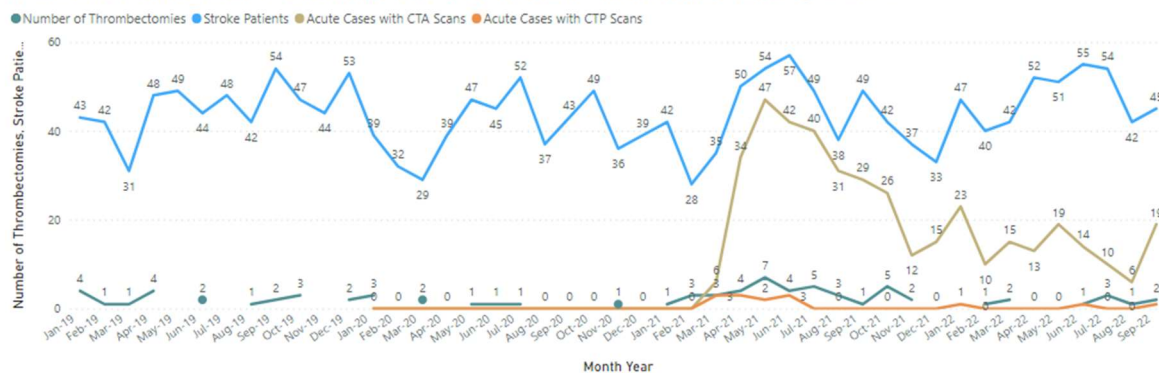
1 site has shown an increase to their scan to MT time (University College London Hospital).

Below we have compared for a selection of the sites, the trends in scan to MT time alongside usage data. In these examples, we have chosen to present the number of CTA and CTP scans that are processed by e-Stroke in each site. We have chosen to include CTP modality as this is available at all CSCs and is used to determine a patient's eligibility for mechanical thrombectomy more than 6 hours after onset of symptoms.

The Royal Sussex – Hub – Sussex ISDN

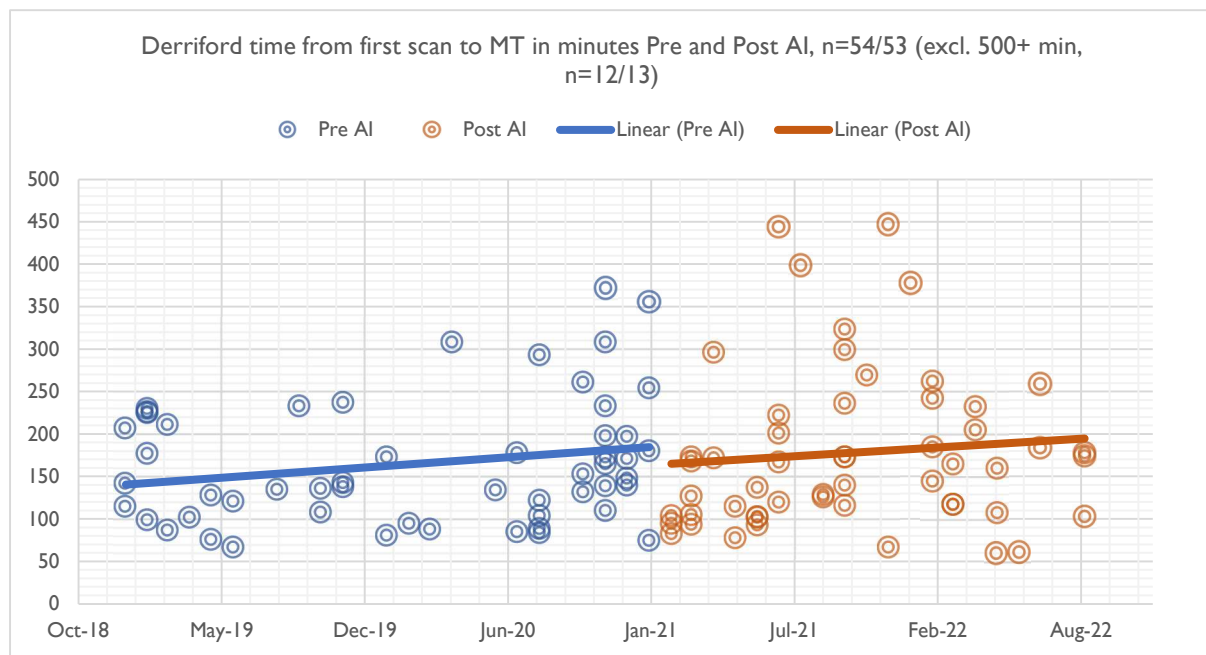


Number of Thrombectomies, Stroke Patients, Acute Cases with CTA Scans and Acute Cases with CTP Scans by Month Year

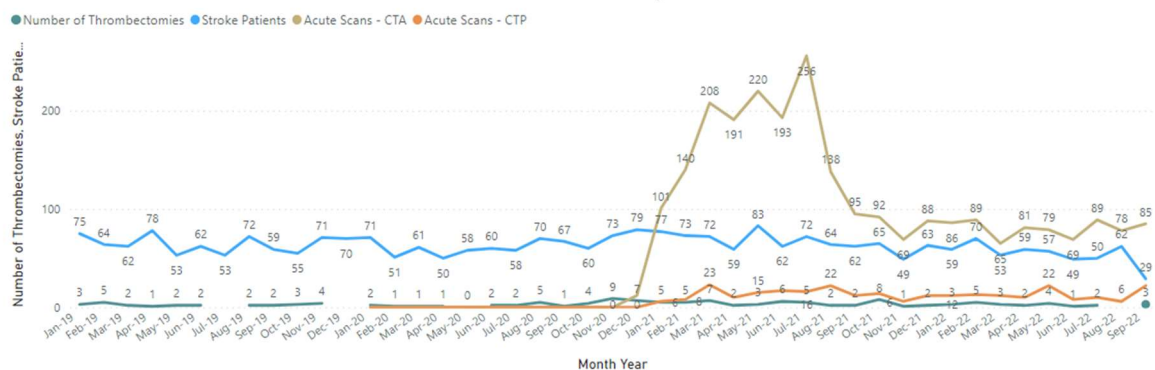


The rate of MTs has increased post implementation by 1.63% and despite the increase in numbers the Scan to MT time remains consistent, showing a slight reduction in scan to MT time a significant shift from pre-implementation of e-Stroke. We know, from our mid-term survey, that the team at the Royal Sussex use e-Stroke for more than 75% of cases. We can assume that sustained and consistent use of the technology at this site has facilitated and expedited treatment decision.

Derriford Plymouth – Hub – Southwest Peninsula ISDN



Number of Thrombectomies, Stroke Patients, Acute Scans – CTA and Acute Scans – CTP by Month Year



We can see that despite the trends indicating that Scan to MT times are increasing, they do remain fairly consistent at this site. The number of scans processed by e-Stroke here is interesting but does indicate that automatic processing of images was introduced in October 2021, so although this looks like a significant decrease, this would have a positive effect on the pathway as automatic processing is quicker.

According to our survey results, the team at Derriford refer to e-Stroke in less than half of cases and they use the software in parallel with the PACs system as the images open automatically. We know that e-Stroke has been fully integrated into clinical practice by the Interventional Neuroradiologists that run this service, but there is more variable use by the stroke and medical registrars.

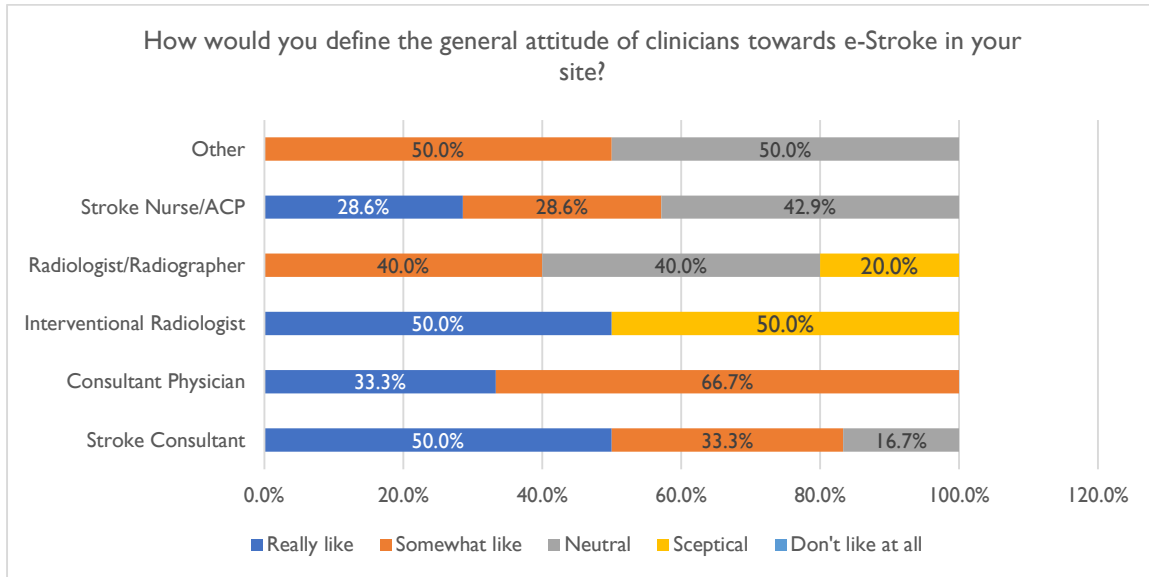
Key points

- E-Stroke has the biggest impact on decision to treat times at ACSs, the use of the software supports the quicker review and acceptance of patients at a CSC.
- Consistent use of e-Stroke is more effective in speeding up the decision to transfer patients for MT.
- Ambulance delays, including waiting for ambulance to transfer the patients to a CSC which is included in the door in door out time, mean that any small gains in decision making may be somewhat neutralised.
- Amongst the benefit for hubs is the ability to communicate with the spokes to expedite review and acceptance of patients to transfer.

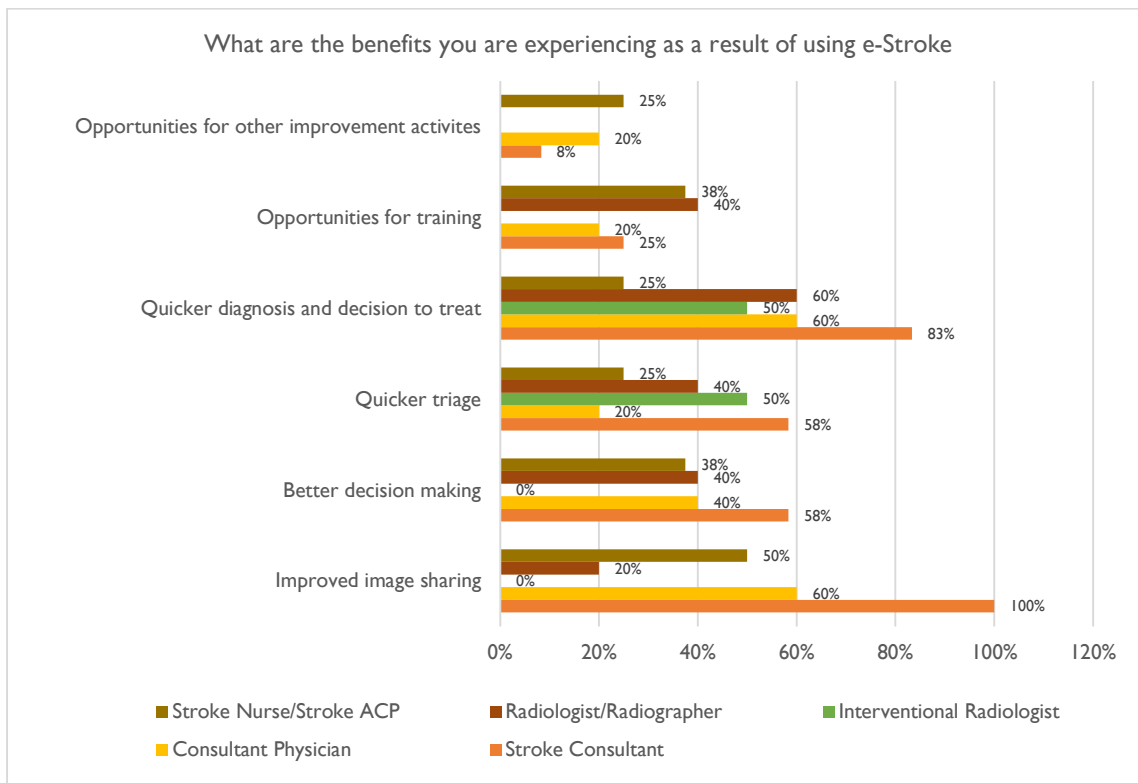
3.2. What are the outcomes for clinical, social, experiential and/or operational effectiveness? (Theme – Effectiveness)

Experiential and Operational outcomes

The general attitude toward e-Stroke is a positive one with 68% (21/31) respondents, liking or really liking the technology.



Stroke clinicians have reported overall that there are many benefits to the introduction of e-Stroke in the acute stroke pathway. Stroke clinicians attribute most value to the improved image sharing and quicker diagnosis and decision to treat is valued the most across all professions.

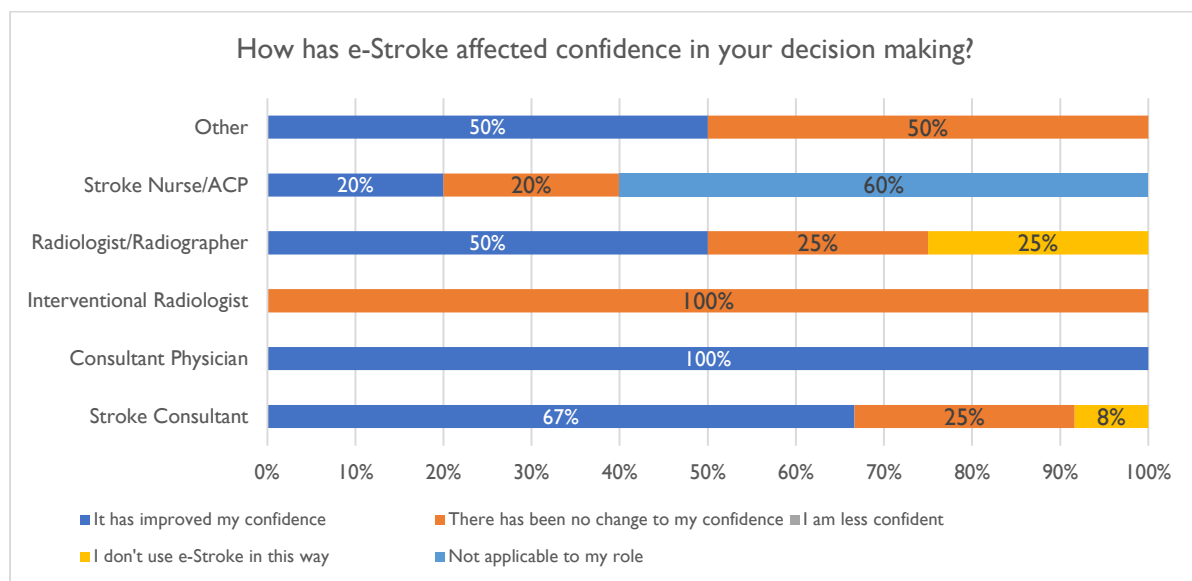


The ability of e-Stroke to facilitate the diagnostic and decision-making process, generally improves clinicians' confidence, especially for more junior and less experienced staff as it provides reassurance in nuanced decision making. This has contributed to faster decision to treat and door in door out times. In addition, beyond

contributing to improved work life balance (especially when clinicians are on call to access to images through the e-Stroke app), the technology creates opportunities for training and quality improvement activities, empowering staff.

When asked to comment on the benefits of the technology on diagnosis and treatment decisions, clinicians referred to improved early detection through rapid image evaluation due ease of access, especially when image sharing is required. Clinicians find e-CTA particularly useful for detection of LVOs and treatment decisions for mechanical thrombectomy. The increase in mechanical thrombectomy rates is in fact seen as the main impact of e-Stroke. While e-Stroke has generally contributed to increasing confidence among clinicians, a minority of our survey respondents (especially stroke consultants with higher levels of experience) argued that the technology does not improve confidence due to accuracy concerns. These mainly concerned e-ASPECTS and e-CTP. Overcalls on e-ASPECT was a particular issue as suitable patients for thrombolysis could be missed and not treated as they should be. Concerns around e-CTP were instead mostly related to the technology picking up the wrong side of the brain.

It is due to these accuracy challenges that a minority of clinicians argue that e-Stroke does not improve confidence and instead it has been put forward that it is best to rely on clinical opinion. This reflects a legitimate concern from stroke consultants that less experienced staff may use the technology as a diagnostic rather than a decision support tool. It is important to highlight, however, that e-Stroke has not been developed to substitute the judgement and expertise of clinicians but instead to support the decision-making process, offering an additional level of reassurance. Therefore, if used as it should be as an aid for image interpretation, there is no reason why the accuracy challenges would mean that e-Stroke cannot provide some reassurance and confirmation in the best-case scenario and a good challenge when expert opinion differs from e-Stroke outputs. This seems to be in fact the view of most clinicians as our survey results confirms that 65% (15/23) felt it had improved their confidence.



The benefits and limitations of e-Stroke are to be understood in the context of the stroke pathway, in particular the challenges presented by the ambulance service and out of hours arrangements (lack of specialists available for services that do not open 24hours). Other factors deemed by clinicians to play a role in the impact of e-Stroke included the distance between ASCs and CSCs and technology compatibility (ASCs and CSCs using different diagnostic support software which poses a challenge to image sharing). In addition to these practical limitations and technical issues, clinicians also spoke about intangible factors that can hamper or accelerate effective adoption of the technology. Among these, organisational culture as well as perceptions related to staffing composition and level of experience were cited as important elements to consider. Related to these, one must consider the important role that training plays for maximum uptake of the technology.

Health benefits and outcomes

We have focussed on 2 key metrics when looking at health benefits and outcomes which also form a substantial part of our value and health economic analysis. Firstly, we have observed reported Modified Rankin Scale (mRS) scores in SSNAP for patients undergoing MT. We have looked at pre-stroke mRS scores in comparison for scores at discharge and 6 months discharge, as we know that people are generally considered good candidates for MT if they have a pre-stroke mRS score of less than 2⁵. However, a recent systematic report and meta-analysis¹¹ found that acute ischemic stroke patients with a pre-stroke disability may benefit from MT and patients with an mRS score 2-4 can also have favourable outcomes.

We have also applied our pre and post-test approach to analysing this data to see whether the introduction of AI has shown an impact on patient's functionality post MT. To help understand better if the decreasing rates of IVT are having an impact on patient outcomes we have looked to see if patients who have IVT and MT have better outcomes than patients who only have MT.

Secondly, we have looked at length of stay, again, pre and post implementation of AI to see whether the introduction of e-Stroke has reduced time in hospital following MT.

The analysis below incorporates all evaluation data, and example of more detail of clinical outcomes by site please refer to the ISDN specific report at Appendix A.

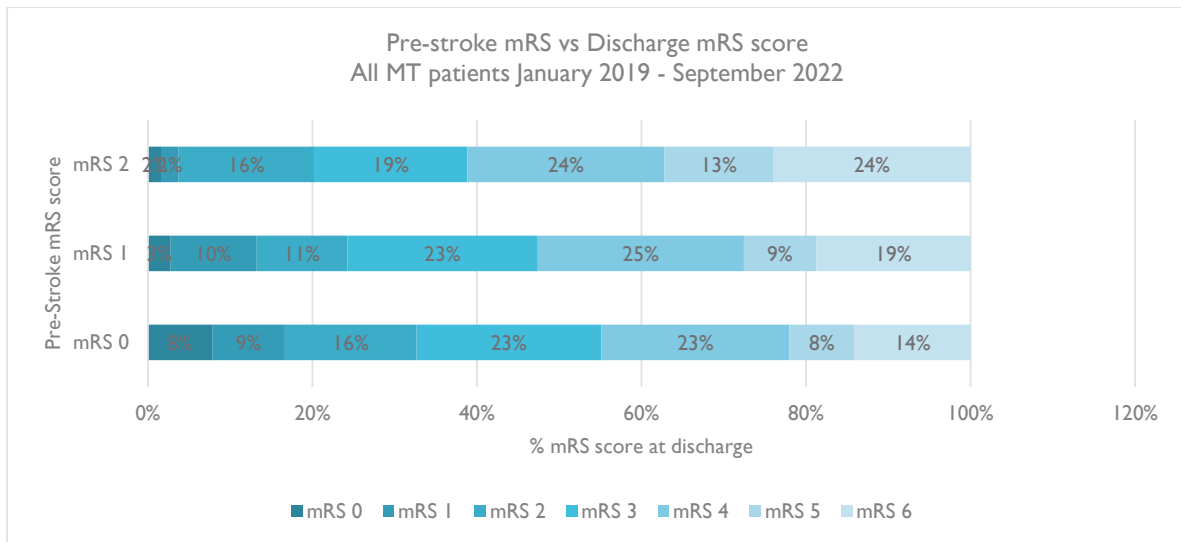
Pre-stroke to discharge mRS score.

Modified Rankin Scale score is a valuable instrument for assessing the impact of new stroke treatments¹². The scoring system is based on global disability, in particular physical disability and the need for assistance with activities of daily living.

mRS 0	No symptoms	
mRS 1	No significant disability, despite symptoms; able to perform all usual duties and activities	
mRS 2	Slight disability; unable to perform all previous activities but able to look after own affairs without assistance	Favourable
mRS 3	Moderate disability: requires some help, but able to walk without assistance	
mRS 4	Moderately severe disability: unable to walk without assistance and unable to attend to own bodily needs without assistance.	Unfavourable
mRS 5	Severe disability; bedridden, incontinent, and requires constant nursing care and attention	
mRS 6	Death	

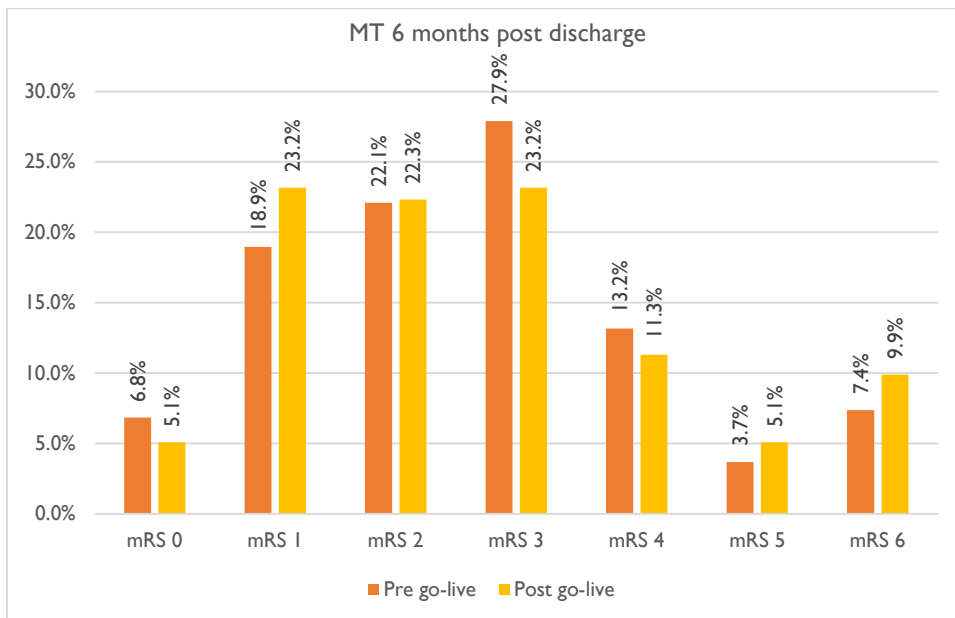
The MR CLEAN Registry¹³ analysis noted a statistically significant shift towards better functional outcome and that in routine clinical practice, endovascular treatment for patients with acute ischaemic stroke is at least as effective and safe as in the setting of a randomised controlled trial. They reported that good functional outcomes (mRS0-2) were achieved in 37.9% in comparison to the control arm 19.1% at 90 days post discharge.

Unfortunately, we do not have access to mRS score at 90 days as this is not recorded in SSNAP (though we do have limited data at 6 months). However, across our evaluation sample population, good functional outcome (mRS score 0-2) was achieved in 528/1832 patients at discharge (28.5%) and we know that with rehabilitation patients' outcomes can improve significantly. Furthermore, our analysis of mRS score recorded at 6 months post discharge, albeit a smaller dataset, mRS score 0-2 was achieved in 270/544 patients (49.6%). The graph below shows us that the more functional a patient is pre-stroke, the better their outcomes will be on discharge.



To determine the impact of e-Stroke on patient outcomes we have further analysed this metric. At the time of discharge, we observed very little difference between the proportions of patients that achieved a good functional outcome (mRS score 0-2) although a slight improvement post implementation did occur. This was 28.2% (170/590) pre implementation compared to 28.4% (358/1262) post implementation. At greater positive effect on patient outcomes post-implementation is seen at 6 months post discharge which is discussed below. At the time of discharge, we also saw a positive outcome on mortality rates which went from 19.3% (114/590) pre-implementation to 15.2% (192/1262) post implementation.

Given the absence of mRS score at 90 days in the SSNAP dataset and the understanding that patient's functionality can improve significantly post discharge with the right care and rehabilitation, we have also looked at mRS score recorded 6 months after discharge, as this is recorded in the SSNAP database.



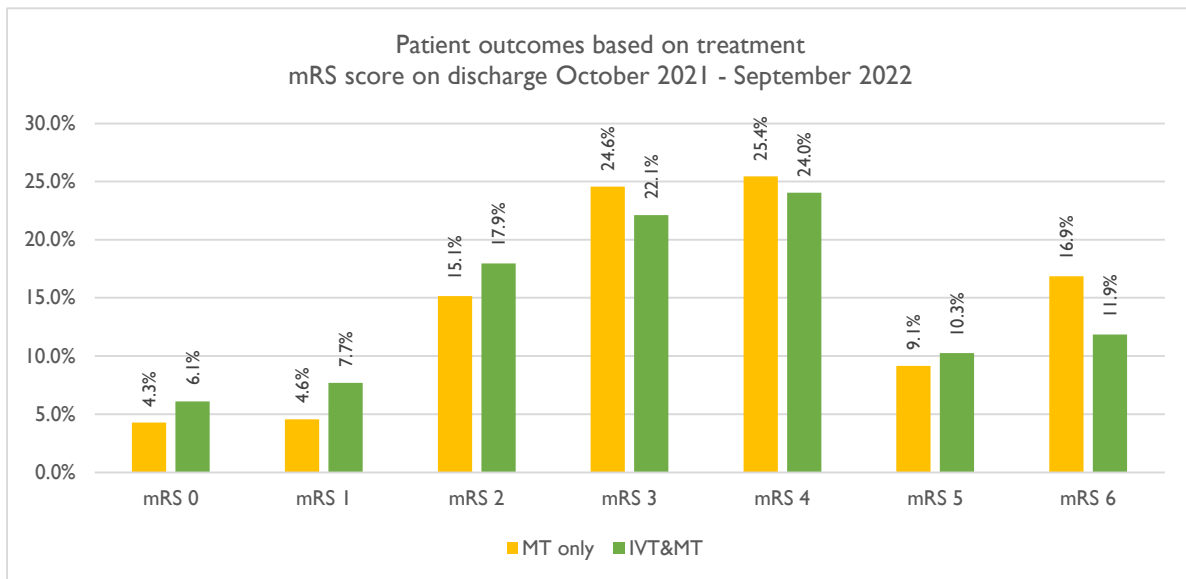
At six months post discharge, we observed that pre-implementation of e-Stroke 47.9% (91/190) of patients achieved good functional outcome (mRS score 0-2), which has improved post implementation to 50.5% (179/354). Interestingly mortality rates (mRS 6) at 6 months post discharge went from 7.4% (14/190) pre-implementation 9.39% (35/354) (9.89%) post implementation.

The absence of data at 6 months post discharge is due to stroke rehabilitation units having capacity and resources to carry out post stroke assessments and then relies on the stroke unit following up to obtain this

information. However, at 6 months post stroke, the introduction of AI has meant that more patients have favourable functionality than before e-Stroke was introduced to the pathway and less people have less favourable outcomes. It is noted that whilst mortality was reduced at discharge it has increased 6 months post, it is therefore important to consider that the introduction of e-Stroke would in part, facilitate the identification of eligible patients that wouldn't previously have been considered for MT.

Patient outcomes based on treatment.

NICE⁵ recommend “Thrombolysis with alteplase as first line treatment for patients with acute ischaemic stroke, and MT together with IVT (if not contraindicated and within the licensed time window) to people who have a LVO confirmed by CTA.” However, we are aware from our analysis of thrombolysis rates that this treatment is declining, it is therefore important for us to understand the impact this may have on the outcomes of patients.



Combining IVT with MT in the treatment of stroke results in 99/312 (31.7%) patients achieving good functional outcomes, in comparison to MT alone 84/350 (24.0%). Mortality rates (mRS score 6) are also better with dual treatment at 37/312 (11.6%) and MT only at 59/350 (16.9%).

It is apparent that patients who are treated with both IVT and MT across our evaluation, have better outcomes than patients who have MT alone, as there is a greater proportion of patients on discharge with favourable functionality and less patients with more severe disability. Treatment with both IVT and MT also results in reduced mortality.

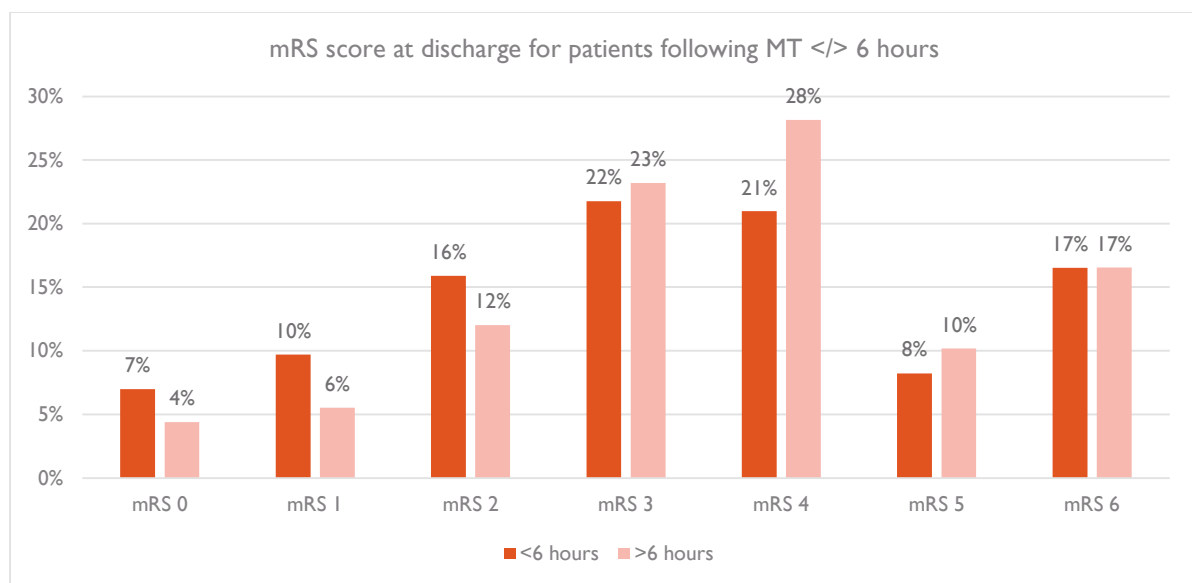
This poses the question if being admitted to an ACS first so that IVT can be commenced and then referred to the CSC for MT is better in terms of patient outcomes than being directly admitted to a CSC and the patient being expedited for MT. Of course, multiple factors play a part in this, such as distance from home to either ASC or CSC, and whether IVT, in particular more novel therapies such as Tenecteplase, could be administered and monitored by paramedic staff to further speed up this part of the pathway.

Outcomes for patients when MT is carried out more than 6 hours after onset of symptoms.

As we have explored earlier in this report, the number of patients undergoing MT more than 6 hours after onset of symptoms has increased over time and since the implementation of e-Stroke. Results from the MR CLEAN-LATE trial¹⁴ demonstrate that patients undergoing MT 6-24 hours after onset of symptoms were approximately 1.7 times more likely to achieve a better functional outcome after 90 days than the control group and concluded that treatment was safe and effective based on the presence of collateral flow on CTA.

We know that the ability to share images more rapidly and the availability of CTP scanning provide the necessary evidence to treat in the extended time window, whereas availability of ambulances services and longer transfer times may mean that patients that weren't intended to be treated outside of the 6 hours window, now are.

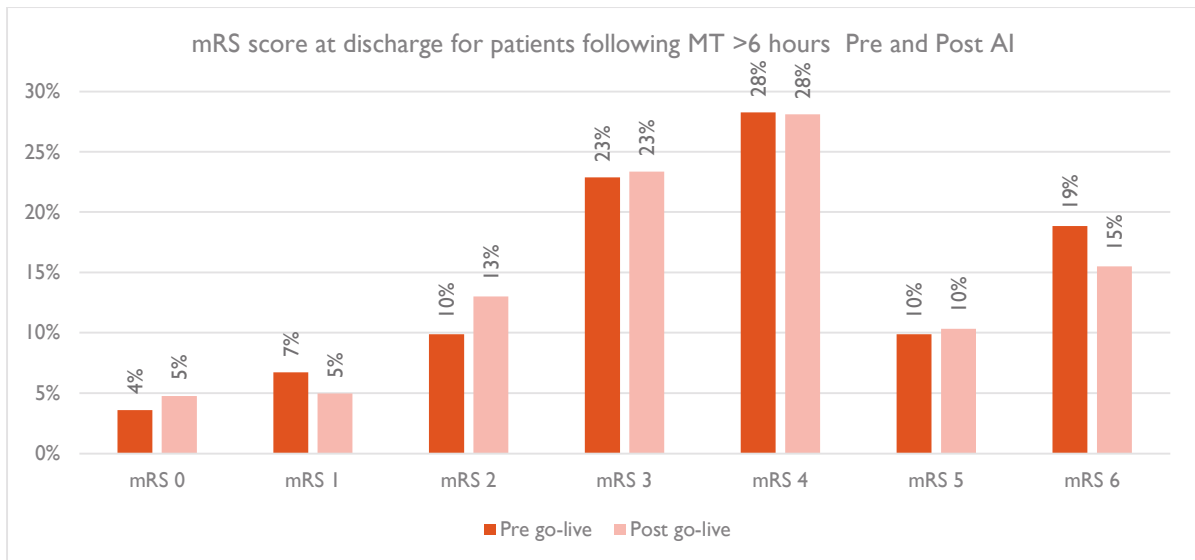
In the MR CLEAN-LATE trial¹⁴, patients with moderate to severe neurological deficit at presentation, were excluded from the trial.



741 patients with MT + 6 hours had their onset to arterial puncture time recorded. Of those 707 had an mRS at discharge recorded. 1145 patients with MT less than 6 hours had their onset to AP time recorded. All had a mRS score at discharge recorded.

As suspected, patients who undergo MT more than 6 hours after onset of symptoms have worse outcomes at discharge than those that are treated within 6 hours, with 155/707 (21.9%) of patients achieving good functional outcomes in comparison to 373/1145 (32.6%). Mortality rates are comparable (mRS score 6).

We now look to see if the mRS score of patients at discharge has been impacted by the introduction of e-Stroke.



239 patients with MT + 6 hours had their onset to arterial puncture time recorded, pre-implementation of e-Stroke. Of those 223 had an mRS at discharge recorded
 502 patients with MT less than 6 hours had their onset to AP time recorded. Of those 484 had an mRS score recorded at discharge

It would appear that post-implementation of e-Stroke, patients undergoing MT more than 6 hours from onset of symptoms have more favourable outcomes (mRS 0-2) 110/484 (22.73%) compared to 45/223 (20.2%) pre-implementation. Mortality rates (mRS 6) have also improved post implementation of e-Stroke from 42/223 (18.8%) to 75/484 (15.5%). We can assume that the introduction of e-Stroke is leading to better identification of eligible patients for MT outside of the 6 hours window. It would also suggest that clinicians are becoming more confident interpreting brain images over time.

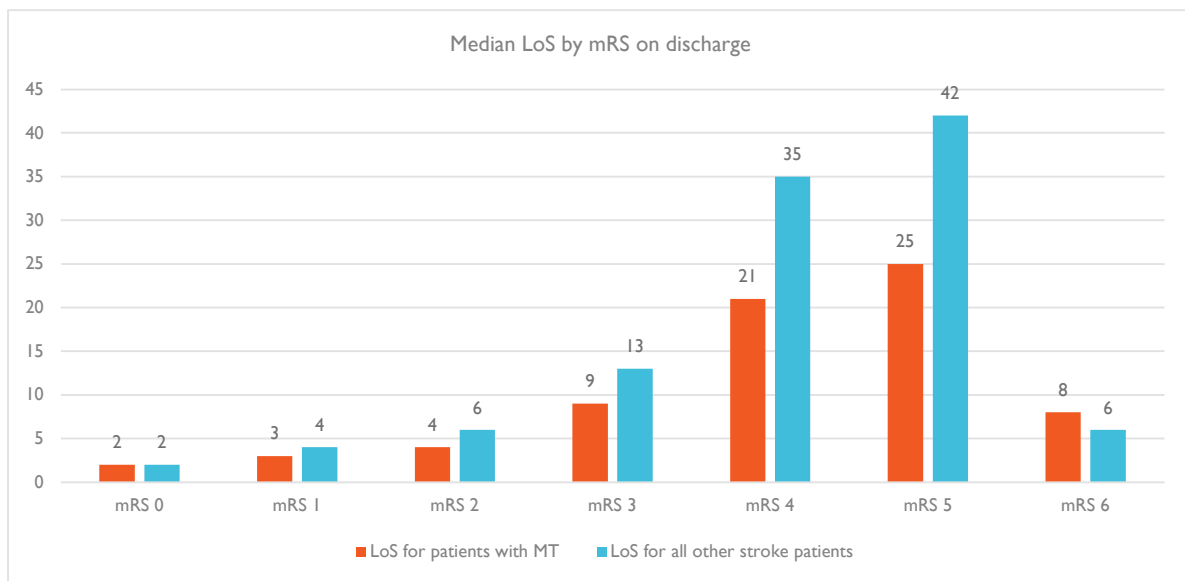
Length of stay for patients following MT



It is important to note that the green line here, incorporates all other stroke regardless of type and severity. However, it is well documented and researched¹⁵ that when patients undergo MT they have a reduced hospital stay, more home time and more favourable living situations. Our dataset takes into account 1939 patients MT and over 60k patients admitted for stroke. The graphs also suggests that length of stay hasn't altered significantly over time so we can come to the assumption that e-Stroke has an insignificant impact on this metric in isolation.

However, as e-Stroke does seem to have an impact on patient outcomes, it is important to understand the relationship between mRS score post-stroke and length of stay.

Length of stay by mRS on discharge.



This graph shows that a post procedure outcome, measured here by mRS score, is linked to length of stay regardless of whether a patient has MT or not, the less favourable the mRS score is on discharge, the longer the stay in hospital. However, patients who have MT the length of stay is longer regardless of the outcome and substantially longer the less functional a patient is following the procedure.

ISDN overview reports, at Appendix A have explored length of stay for individual sites. Further regression analysis on length of stay and mRS score will be undertaken as part of the economic analysis, due to finalised in September 2023, which will aim to address; what effect e-Stroke has on current and future health and personal social care costs and; how do such costs compare with health outcome benefits.

Key points

- General positive attitude towards the inclusion of e-Stroke in the acute stroke pathway, with many benefits realised that confirm improvements to rates and speed of treatment.
- With the right training and support, e-Stroke can improve confidence in decision making.
- Post stroke rehabilitation and care is crucial in patients' recovery, the availability and access to these services is imperative and this should be a consideration when analysing patient outcomes.
- mRS score 6 months after discharge is not recorded well, in part due this is due to lack of capacity in stroke units to carry out follow-up assessments. It would be beneficial for both local clinical audit and quality improvement activities as well as large scale real-world evaluations such as this, if service providers could encourage more consistent reporting of this metric.
- Marginally more favourable outcomes are observed post implementation of e-Stroke.
- Patient outcomes are better when a patient has both IVT and MT.
- Whilst patients who have their MT more than 6 hours after onset generally have less favourable outcomes, the introduction of e-Stroke does seem to have marginally improved these and reduced mortality.
- It is important to consider that the introduction of e-Stroke would in part, facilitate the identification of eligible patients that wouldn't previously have been considered for MT.

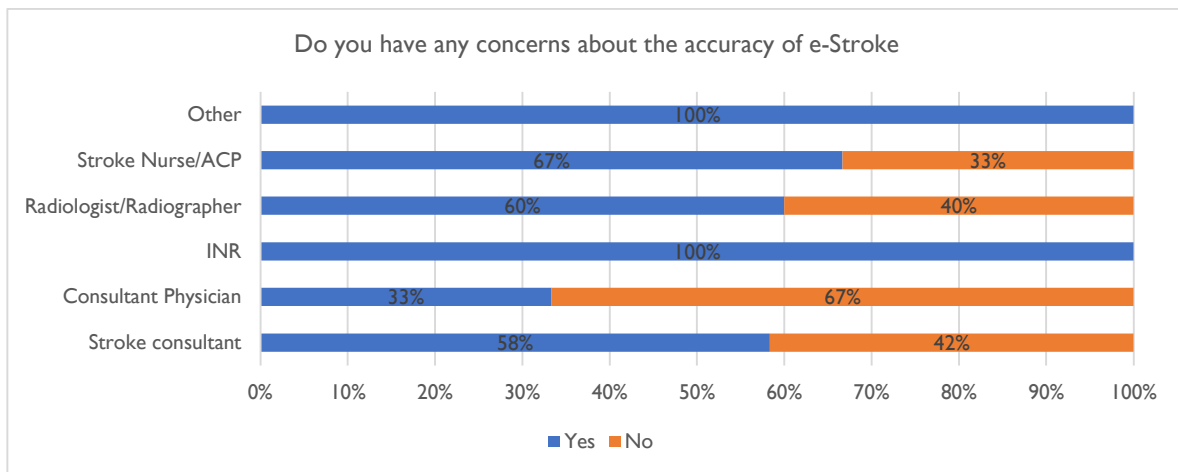
3.3. How accurate is the technology in a real-world deployment environment? (Theme – Accuracy)

In this section, we will explore how the teams using the technology rate it's accuracy and how this affects use. It is important to note, that whilst accuracy is challenged, there is a general consensus that the software is a decision support tool and needs to be viewed in that context and we are not assessing the accuracy of the technology as a standalone system, but one that is designed to be used alongside human assessment.

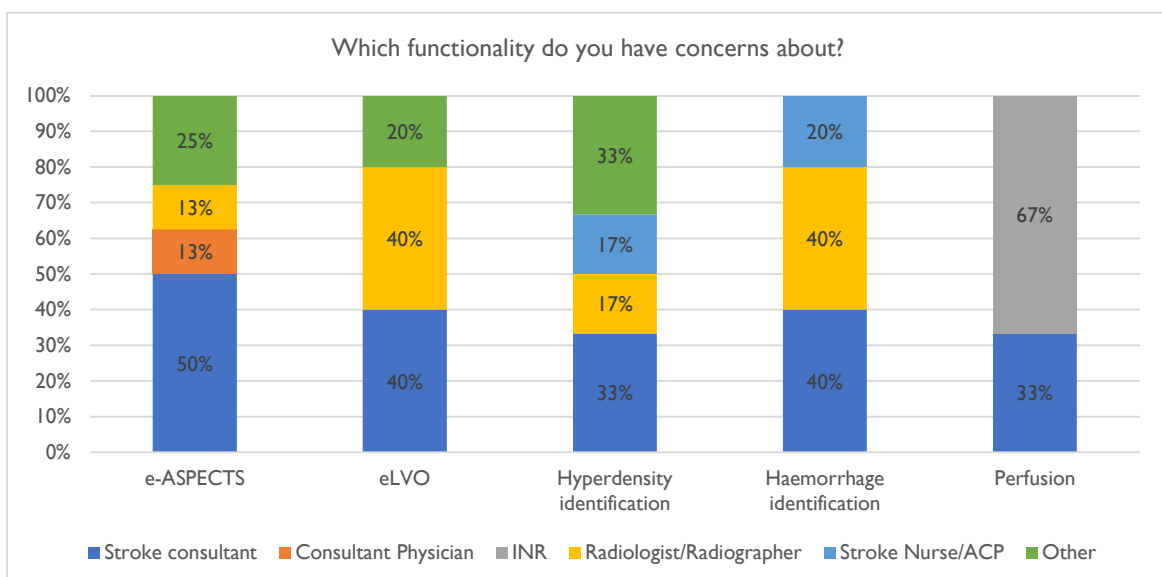
Understanding and converging information from multiple sources are key skills in the clinical decision-making process. If incorporated appropriately, with the necessary training and support to ensure confidence then e-Stroke has the potential to make clinical decision making safer and, when utilised appropriately will make the acute stroke pathway more efficient and improve patient outcomes.

It is important that clinicians understand when e-Stroke should and should not be relied upon and how to modify their decision-making process to take this into account. A summary of experiential concerns with accuracy are discussed below, however, we will carry out further work to determine which aspects of e-Stroke clinicians need to be more mindful of using to support their clinical decision making.

60% of clinicians (15/25) agreed with e-Stroke in more than 75% of cases with a further 32% (8/25) agreeing in more than half of cases. Concerns with the accuracy of e-Stroke differ by clinical profession, with Consultant Physicians being less concerned than others.



Just over half of respondents to our survey (17/32) expressed concerns with the accuracy of e-Stroke. When asked which aspect or functionality they were most concerned about, eASPECTs overcalling (8/28) and hyper density identification (6/28) seemed to be the most concerning.



Further analysis will be conducted on accuracy to determine whether factors such as familiarity with the technology i.e., how long it has been used at a site, and clinicians general experience i.e., length of time in post have an impact on perceptions of accuracy.

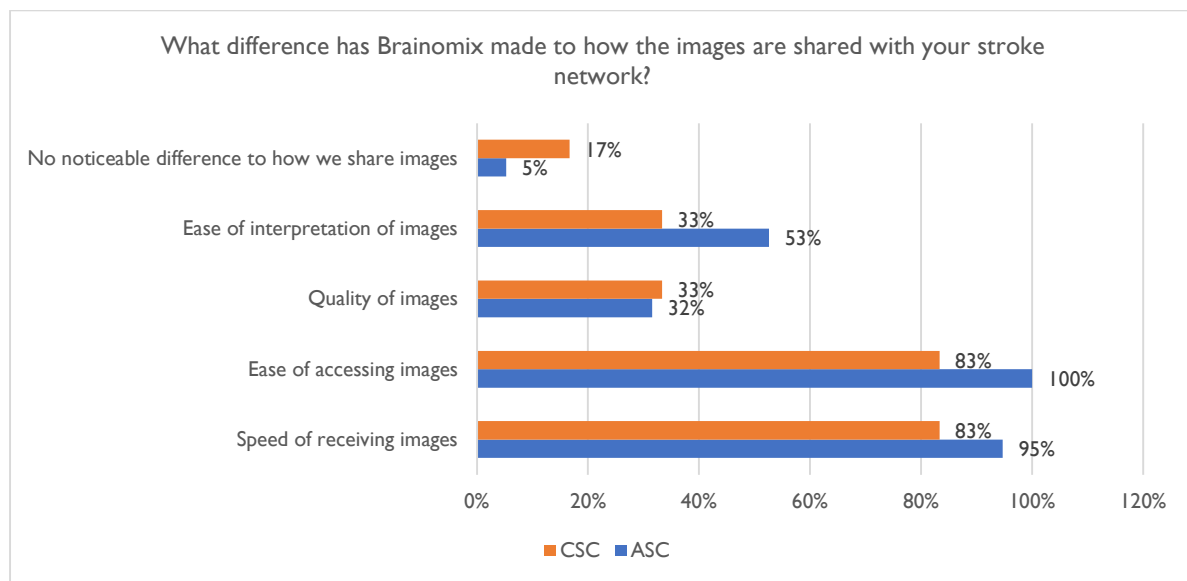
We have found that when discrepancies between clinical opinion and e-Stroke outputs differ that 43% (12/28) review and discuss images at clinical meetings and/or with Brainomix, with a few sites carrying out their own accuracy audits. However, as discussion of discrepancies doesn't seem to be widespread, this should be progressively encouraged. Inbuilt functionality with e-Stroke allows the clinician to instantly report any shortcomings directly to the clinical and software 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. Education and training, as expected, is key, particularly to manage the expectations of the users and potential users regarding the intended use.

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

e-Stroke by Brainomix is a CE-marked collection of tools that use AI algorithms to support stroke clinicians by providing real-time interpretation of brains cans to help guide treatment and transfer decisions for stroke patients, allowing more patients to get the right treatment, in the right place, at the right time. It is important to note that the technology is not just AI image interpretation. The e-Stroke platform, including a mobile phone app and web user interface supports the ability to communicate with other sites and clinicians in and out of hours, facilitating the quick and easy transfer of CT, CTA and CTP scans.

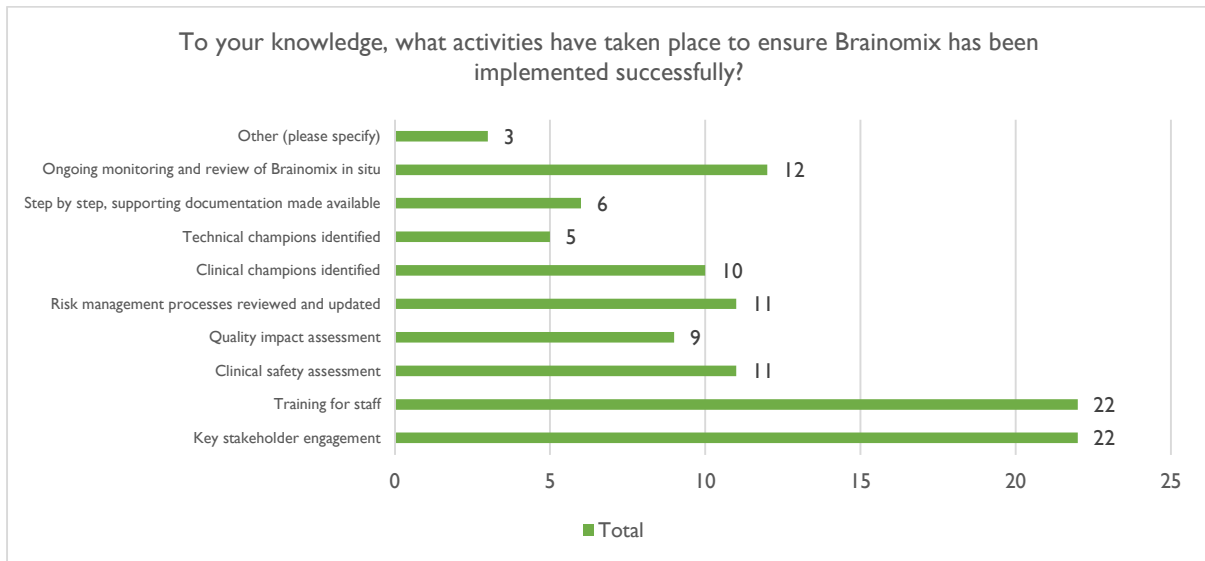
When asked what difference e-Stroke has made to how images are shared with your stroke network, the response is categorically positive, with only 2 respondents not noting any positive change.



As we have discussed earlier in this report, technically, e-Stroke is deemed to identify more eligible patients for MT and speeds up the decision to transfer or proceed with MT, however, the benefits of sharing images are deemed equally if not more important with the vast majority of people citing the speed at which images are shared and received and the ease of accessing images as having a positive impact to sharing images across their networks.

3.5. What are the key risks and what assurance/management is in place? (Theme – Safety)

A key aspect of assurance and management is to ensure that technology is implemented and embedded successfully into normal clinical practice. We have found that a variety of techniques have happened to ensure the seamless implementation into the existing stroke pathways, as detailed in the graph below.



Training plays a significant part in ensuring the technology is implemented successfully 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.

The technical team also offered teaching lessons face to face which has been of great help to users of e-Stroke. One site has been able to produce 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.

Beyond the support currently available to clinicians, there is a need to introduce more formal processes to intervene promptly when technical challenges arise to avoid risking delays in diagnosis and treatment. In addition to processes designed to tackle technical challenges, we have identified that there is a need for introducing protocols for reconciling clinical opinion with e-Stroke outputs when discrepancies are found.

Continued collaboration between users and e-Stroke would also offer opportunities to reconsider some of the clinical risk management processes needed when relying on a decision support tool like e-Stroke. Since its introduction, 67% (12/18) of sites have reviewed their risk management processes with only 2 making any changes, and the remaining sites recognising that this still needs to be reviewed. While this may be justified by the fact that clinicians often interpret scans first before referring to e-Stroke outputs (therefore only using the technology as a form of assurance to support their decisions), it is important to highlight that there are still clinicians who open scans and e-Stroke outputs in parallel, and those that, during out of hours, may be referring to images via the smartphone app. This poses a potential level of risk which may require more targeted risk management processes than those that existed before the technology was introduced.

We will continue to work closely with e-Stroke to understand their training offerings, particularly when new versions are released. We will also work with the NHS sites in the evaluation to understand better how safety incidences are reported both internally and to Brainomix.

3.6. Is each module of the technology compliant with the most appropriate reference standard for accuracy and safety? (Theme – Safety)

e-ASPECTS and e-CTA are certified Class IIa products by the MHRA. ISO/IEC 27001

3.7. What is the effect of the AI technology on current and future health and personal social care costs, and; How do costs compare with health outcome benefits (Theme – Value)

We are still in the process of gathering important information on both evaluation questions relating to value, which will be addressed the health economics report due in September 2023. To follow is an overview of approach in which we will consider the overall methodology; value of unit improvements; calculations of impact; and scenarios of value.

Our overall approach is that value is calculated as:

Impact of the technology on outcomes; multiplied by the Value of a unit improvement in those outcomes; less any extra Costs associated with the use of AI.

In undertaking these calculations, an important consideration is to identify which outcomes are most important from a value perspective. Our work has identified three such agendas:

- Reductions in costs for acute care if there is a reduction in length of stay due to faster time to surgery following a stroke that would benefit from MT;
- Reductions in costs for social care if there is an increase in the proportion of patients being supported to stay at home;
- Improvements in wellbeing if there is an increase in the mRS score of patients at 90 days and subsequently due to an increase in appropriate use of MT.

The impact on these three key outcomes will be calculated through regression analysis. This aims to investigate changes in the relevant outcome due to the implementation of e-Stroke - compared to a counterfactual in which the e-Stroke technology was not used – which requires us to take into account other influencing factors such as the covid pandemic, and changes in clinical pathways. This requires a relatively complex model to be developed, detailed below.

The required assessments of value are then:

- Reduced length of stay - value per patient is equal to change in number of bed days per patient multiplied by cost per bed day (assessed from HES data, which is available by site by time period);
- Higher proportion staying at home – value per patient is equal to change in proportion of patients supported to stay at home multiplied by saving in social care when patient is supported to stay at home. In terms of social care costs, we will draw on research presented in Jones et al (2022)¹⁶ [the “PSSRU Unit costs manual”] and Luengo-Fernandez et al (2013)¹⁷
- Wellbeing value of improved mRS - calculated as the unit value of an improvement in mRS scores due to appropriate MT multiplied by the average improvement in mRS after implementation of appropriate MT. In doing so, we will draw on estimates in Lobotesis et al¹⁸ on average QALY scores per patient for outcomes at 1 year, 2 years, 5 years and lifetime (i) for Stent retriever plus IV-tPA; and (ii) for IV-tPA alone.

A further crucial parameter for our value assessment is the time period for consideration of costs and benefits. The paper Luengo-Fernandez et al (2013)¹⁷ had a follow-up period of five-years for reviewing patients, and we believe that this is a suitable time period for our economic assessment.

Costs information

The assessment of extra costs due to the introduction of AI technology will be taken from site surveys, interviews, and e-Stroke data. Our assessments will consider useful research data on the cost of mechanical thrombectomy. For the non-AI approach, we have calculations indicating a mean total cost of providing MT and inpatient care within 24 hours of £11,780 (this estimate is subject to change based on any new information on substantive changes in MT treatment occurring since 2015-2018, which is the period that the underpinning research examined).

Our perspective on MT costs under the AI-augmented approach will be based on the above, adjusted for AI software and equipment, staff training costs and required/recommended changes to standard operating practice that have staff cost implications.

Calculating impact on outcomes

We next turn to consideration of how impact on outcomes will be calculated. As we do not have a direct control group (i.e. patients in hospitals without e-Stroke in the time periods that we cover); instead, we have data for patients for our selected hospitals for a time period that covers pre and post implementation of e-Stroke. We use the statistical approach of regression analysis / logistic analysis² to determine impact, by considering changes in contextual factors for patients, in order to isolate the effects on these outcomes due to the implementation of e-Stroke. The table below shows the statistical technique and types of effects considered.

	Time to decision	No. treated with MT	Length of stay	Stay at home	mRS
Type of statistical analysis	Linear regression	Logistic analysis	Linear regression	Logistic analysis	Linear regression
Issues taken into account					
- Site characteristics (IMD, Rurality, Scale, ASC/CSC)					
- Transfer time					
- Patient characteristics (Age, gender, co-morbidities)					
- Context (Covid, regional ambulance times)					
- Pathway variations					
- AI implementation					

We will compare the results of this analysis against findings of the academic literature as to the extent to which MT (a) reduces length of stay for patients where clinically justifiable; and (b) increases the proportion of patients able to stay at home.

It should be noted that the analysis may not find a direct improvement in length of stay and mRS with the introduction of e-Stroke (compared to pre-implementation parameters), but this is still a benefit if it leads to an increase in the number of appropriate MT treatments undertaken, since research shows that such treatments are beneficial in terms of mRS compared to those that do not undergo such treatment³. The approach set out here enables us to take into account (a) the outcomes of those that undergo MT using Brainomix and (b) to make allowance for those that could have undergone thrombectomy but did not.

A further point to note is that while we may not find a direct link when examining changes in mRS, we may find a statistically significant link in terms of time to decision – in which case we can then infer a potential for improvements in mRS from the strong evidence base that connects time to decision and mRS⁴.

Scenarios of value

Our starting point is the current approach (as of 2022/23) with current conditions – this shows the position with substantial implementation of e-Stroke – though not achieving its full potential.

² when there is a limited number of outcomes, most notably a yes/no answer, a logistic regression approach enables us to predict probability values for the outcomes. The model identifies the "Odds Ratio" for the way that characteristics influence the likelihood of the outcome, with results of the type: "Other things being equal, being in age group 65 to 69 increases the time to decision by xx%".

³ The paper Lobotesis et al (2016)¹⁸ has estimates for clinical efficacy in terms of mRS scores, based on findings from the USA SWIFT PRIME trial (if in the 0 to 6 hour window). The paper looks at the probabilities of each mRS scores at 7 days, and then also for mRS scores at 90 days, (i) for Stent retriever plus IV-tPA; and (ii) for IV-tPA alone.

⁴ in particular, we aim to use a relationship between time to treatment and key outcomes following stroke set out in Hargroves and Lowe (2022)²⁰ (p44)

We then compare this base case with four scenarios to gain a perspective on what benefits e-Stroke is achieving, and what could potentially be achieved:

- Pre-implementation with previous conditions and no implementation of e-Stroke – this sets out the unadjusted baseline that was operational as of 2019 or so;
- Pre-implementation with current conditions and no implementation of e-Stroke – this is intended to estimate the level of MT and corresponding benefits that would have occurred in the baseline period if it had contextual factors (such as ambulance service performance) equal to those occurring in 2022 – this is the adjusted baseline that we use to compare with current performance to assess the impact of e-Stroke;
- Optimistic model - current conditions with relatively feasible improvements to pathways and fuller implementation of e-Stroke – this is the scenario which, when compared against the adjusted baseline provides a way to assess the (constrained) potential impact of e-Stroke;
- Utopian model – based on current conditions with ideal improvements to pathway arrangements, this is the scenario which, when compared against the adjusted baseline provides a way to assess the full potential impact of e-Stroke.

Sustainability of e-Stroke

While the purpose for this evaluation has been to assess the extent to which e-Stroke is impacting on clinical outcomes, the focus has also been on enablers to implementation to help sites introduce the necessary conditions for successful sustainment and scale up of the technology. Sustainability and success of e-Stroke is highly dependent on the extent to which site-specific conditions, such as pathway configuration, staffing arrangements, demographic factors and culture are being considered as the technology gets embedded into the hospital. As far as opinion of clinicians is concerned, 86% (25/29) users of the technology are keen to continue using e-Stroke beyond the trial, with a further 10% (3/29) yet to decide.

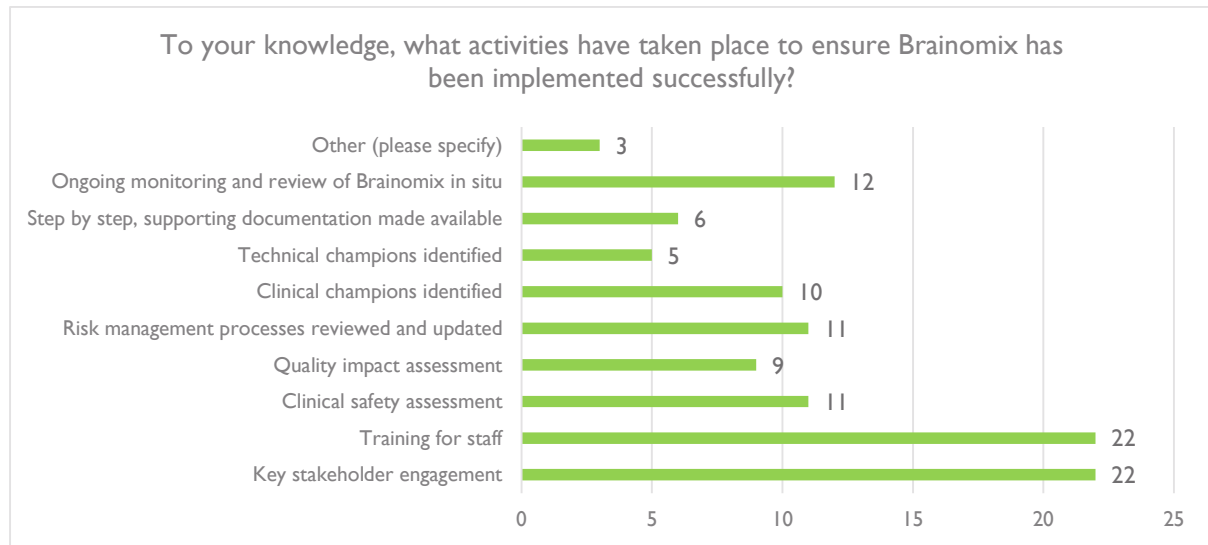
While e-Stroke has demonstrated to have widespread benefits, it is key to consider how hospital-specific characteristics these may facilitate or hinder its adoption and effectiveness, especially when considering the future of the technology and its sustained use within the acute stroke pathway. To determine the impact of variation across sites we have clustered the hospitals based on carefully selected characteristics, in order to develop recommendations to support quality improvement activities.

When asked what factors had hampered the implementation and use of e-Stroke, staffing and workforce factors were deemed to be the most obstructive along with IT networks and configuration.

As mentioned above, clinicians see a potential for e-Stroke to encourage training alongside other quality improvement activities that can maximise the efficiency of the stroke pathway. However, to date, minimal efforts and resources have been invested in quality improvement activities that can help optimise the benefits of the technology as this is the first evaluation that is exploring the role of quality improvement from this lens. It is important to highlight however that there is potential for the introduction of quality improvement initiatives, especially in the context of the efficiencies that e-Stroke is creating in the system due to more junior staff increasingly requiring less support from more experienced clinicians as a result of the guidance the technology provides for image interpretation. While we will not dwell on quality improvement in this section, it is worth recognising that these efficiencies resulting in cost savings could be redirected to explore how to overcome some of the limiting factors for stroke outcomes, notably the current challenges with the ambulance and rehabilitation which, continue to neutralise the benefits of the technology.

It is through the development of targeted guidelines that appreciate the specific contexts in which sites operate that targeted quality improvement activities for clinical outcomes can be introduced. To do this effectively, it is important to differentiate between any intrinsic characteristics that make certain outcomes more or less achievable and practices that can be reconsidered and adapted to improve results. Hence, our profiling approach has looked at both 'static factors' that are inherent to a site (such as hospital size, location, local deprivation levels) and pathway characteristics (site-specific practices that can evolve over time) to establish how sites with more or less favourable starting positions can optimise the benefits of Brainomix through quality improvement activities for improved clinical outcomes. This has opened up discussions around funding and resourcing as it relates to identifying targeted areas for improvement that are likely to guarantee results within specific clinical settings. Alongside the generation of quality improvement recommendations, encouraging sites to share their insights and suggestions for effective implementation of the technology has

been core to this process. Hence, we have been gathering suggestions that are informing our thinking around adoption and sustainability of Brainomix. Below, you can see the range of initiatives that have been introduced to ensure the technology would be implemented effectively and the key factors that have hampered its use:



Given the long-term nature of this evaluation, we are making it a priority to provide timely findings and recommendations that can be used by sites to optimise the impact of the technology as it is being evaluated. Therefore, we have decided to adopt an iterative approach, recognising that our profiles and recommendations will evolve over time as additional and more granular data becomes available. **Our first profiling iteration is based on pre-implementation site aggregate data which offers a snapshot of site clusters before implementation of e-Stroke.** We have used this first set of profiles to determine which sites were in a more or less favourable starting position for the achievement of specific clinical outcomes and to identify pathway adaptations that, in conjunction with the use of e-Stroke, may allow sites to improve their performance.

While our first iteration does not yet consider post-implementation data, it still provides important insight into the factors that are most likely to hinder or facilitate outcomes, offering therefore early insight on how sites may be able to optimise the pathway for greatest impact of the technology. What this first iteration does not do is offer targeted quality improvement recommendations for specific sites. This will be the scope of our second iteration which will be presented in the final report. By comparing pre and post implementation data at patient level, the second iteration will provide a granular and accurate trajectory of performance. The refined clusters resulting from this more in-depth analysis will supersede those from the current iteration and will enable us to confidently produce a targeted set of guidelines for impact maximisation. This will be based on an assessment of how different typologies of sites starting from more or less favourable conditions may have been more or less successful at optimising the impact of Brainomix and maximising their clinical outcomes.

The model we have developed for our first profiling iteration and the regression analysis findings that are presented below will be used for the next iteration which we plan to generate very quickly following this report. It will be necessary to test our findings with our working group and wider cohort of clinicians for our pre and post implementation findings to be validated. This is planned for June.

Regression analysis results:

We have found a useful set of (statistically significant) relationships that are shaping our understanding of how different site profiles perform against specific indicators. Our analysis has revealed that:

- Hospital volume (number of spells) appears to lead to improved effectiveness in several important outcomes – speed of treatment, proportion given thrombolysis, discharges to home
- Social prosperity appears to be having an effect on some outcomes, notably length of stay and proportion of eligible patients given thrombolysis
- mRS scores are influenced by a range of factors including case mix, volume and the urban/rural nature of the catchment area

We believe that this analysis presents a starting point for further investigation at both a qualitative perspective (through interviews and pathway analysis) and quantitative analysis at patient level.

Emergent site clusters

Sites have been grouped into 6 clusters reflecting the three most important underlying (static) factors affecting outcomes. The choice of these underlying factors – level of rurality/urbanicity, social deprivation and volume of stroke cases – has been based on statistical analysis (linear regression) on site aggregate data.

Each site has been allocated a cluster depending on whether it counts as High/Low against a given underlying factor (e.g. High / Low volume of cases).

Hospital
Large, rural, less prosperous
Derriford Hospital
Eastbourne District General Hospital
Royal Cornwall Hospital
Torbay Hospital
Large, rural, more prosperous
Colchester General Hospital
John Radcliffe Hospital
Northampton General Hospital
Royal Devon and Exeter Hospital
Southend Hospital
Large, urban, less to more prosperous
Queens Hospital Romford HASU
Royal London Hospital HASU
University College London Hospital (UCLH)
Royal Berkshire Hospital
Wycombe General Hospital
Small, urban, less prosperous
Darent Valley Hospital
Great Western Hospital Swindon
Royal Sussex County Hospital
Worthing Hospital
Small, rural, less to more prosperous
Ipswich Hospital
Maidstone District General Hospital
Milton Keynes General Hospital
St Richards Hospital
East Kent University Hospital
North Devon District Hospital

Based on our first iteration model, each site has been given an expected and actual value for each of the key performance indicators mentioned above (length of stay, proportion receiving mechanical thrombectomy where appropriate etc) based on the statistical analysis informing choice of underlying factors. Sites have been assigned a given colour relating to their cluster, so that one can view the range of outcomes for a given cluster. For further details, please refer to the example in appendix 1B which shows performance against expected on the basis of the linear regression coefficients.

Please note that the expected y-value takes into account relevant underlying (static) factors that are statistically significant for this performance measure. Difference in y-value and expected y-value show how far from the expected value the site is. Where a bigger level is better (e.g. % of cases that receive mechanical thrombectomy where appropriate) those that have negative values are under-performing and those that have positive values are over-performing. Where a lower level is better (e.g. length of stay) those that have negative values are over-performing and those that have positive values are under-performing.

Outliers and performance

For each performance factor, we have identified outliers, sites that performed either well above or well below average before implementation of Brainomix. For each outlier, we have explored potential factors that may have hindered or facilitated clinical outcomes. There are several pathway variations that we think may have played an important role. These include:

- relying on video triage or a phone call between paramedics and stroke consultants before admission (instead of a standard pre-alert)
- patients being taken to the hyperacute stroke unit instead of the emergency department
- ambulance waiting times
- workforce availability, e.g. having a dedicated stroke consultant, specialist radiologist/INR and/or stroke nurse
- CTA being requested automatically alongside CT
- Having access to CTP
- Thrombolysis being administered in CT
- Arrangements being in place for quick transfer to the CSC, e.g. admitted ambulance crew waiting at the site for patient transfer, ability to transfer patients for MT while on thrombolysis, limited opening hours of the thrombectomy service

In addition to these pathway variations, there are other factors that need to be considered when trying to explain outliers. We know for instance that some ISDNs have been established before others, enabling sites to collaborate much more closely together. System conditions like this play an important role in site performance. As mentioned above, our plan is to work closely with clinicians to explore the wide range of factors that may have contributed to differences in outcomes and to the unique journey we will capture for each site through comparative analysis of pre and post implementation data.

4. Conclusions and next steps

We found that clinicians find e-Stroke acceptable and of benefit to the acute stroke pathway. Whilst the technology is easy to use, with some noting issues with accuracy, the vast majority deem improved data and image sharing as well as better communication between referring and accepting sites as a huge improvement to previous processes and pathways. This coupled with a great appreciation for the high standard of training and responsive support that Brainomix offer, has resulted in e-Stroke contributing to the increased rates and speedier decision times of mechanical thrombectomy across our evaluation sites.

Clinical training for teams at acute centres, where required, is recommended and will improve the effectiveness of e-Stroke, both in the decision to proceed with CTA scans but also in the ability to quickly identify eligible patients for IVT and MT, speeding up the decision to discuss transfer with the CSC.

Ambulance availability may neutralise the impact of e-Stroke, as will lack of adherence to the NOSIP, in particular acquiring all available images. Decision to carry out MT is reliant on CTA and in some cases CTP brain scans,

As there are still variances in our knowledge about sites, we plan to continue our formative feedback as to increase our experiential evidence of e-Stroke. This will help us to understand if opinions have changed over time and further support our quantitative findings. We will also determine if there have been any other significant changes to the acute stroke pathways that may effect the impact of e-Stroke.

Further analysis of SSNAP data will be undertaken to determine whether e-Stroke is more or less impactful at certain times of the day or week i.e. in hours vs out of hours.

Our value proposition will be presented in through Health Economics work, due to be reported in September 2023.

5. References

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6. Appendices

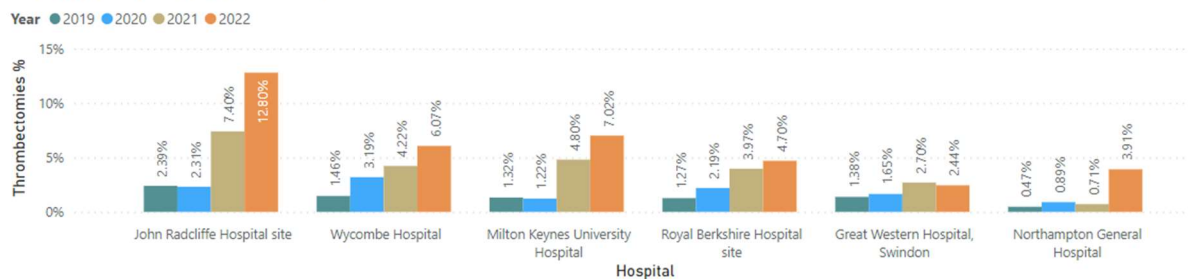
APPENDIX A – Example ISDN overview report

TITaN Network Overview

- Great Western Hospital
- John Radcliffe Hospital
- Milton Keynes University
- Northampton General
- Royal Berkshire Hospital
- Wycombe Hospital

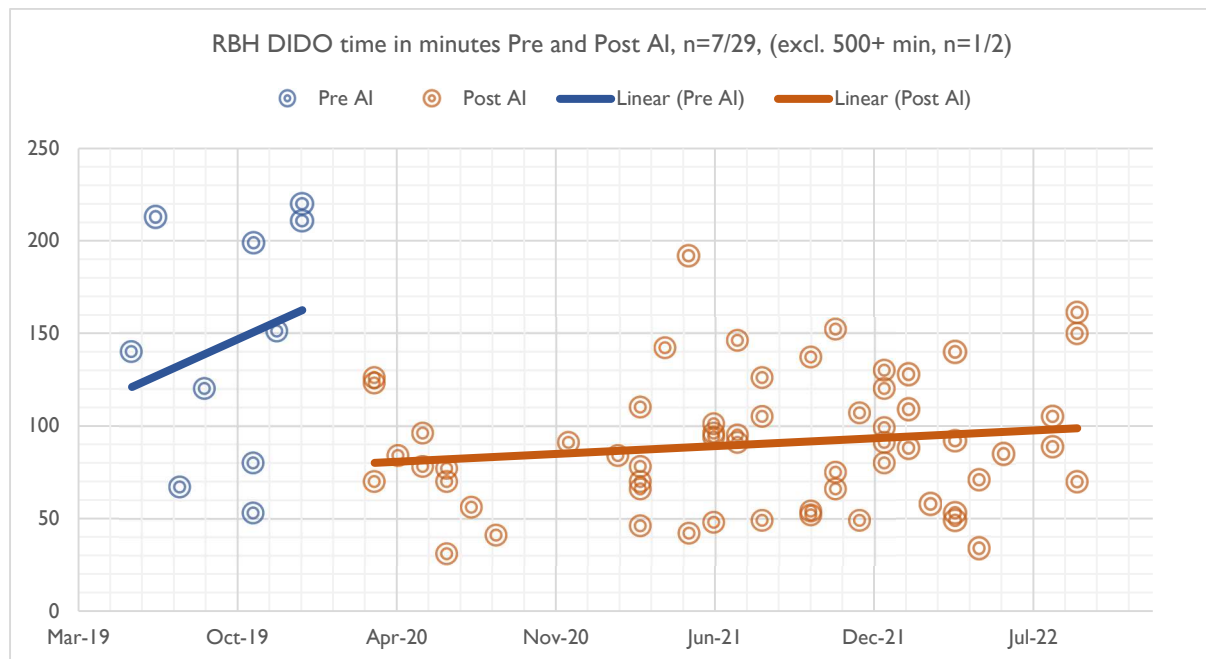
Network Overview of rates of Mechanical Thrombectomy

Thrombectomies % by Hospital and Year



This chart shows the annual MT rates at each site of this network (although only 6-months data in 2022 is available). In virtually all cases there is an increase in MT rate with time. The John Radcliffe is on course to exceed the 10% MT target in 2022 (with a rate of 12.8% at the end of Q2).

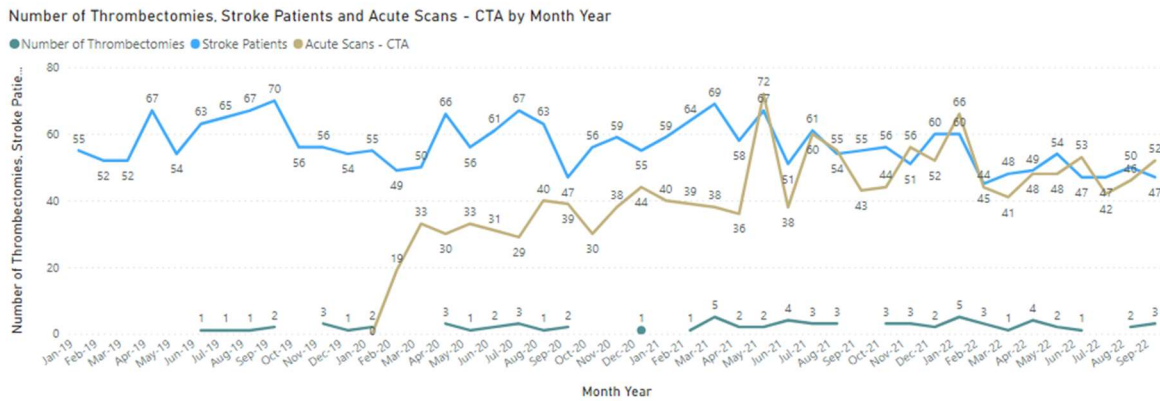
Royal Berkshire



The chart indicates that before e-Stroke (Jun 19 to Jan 20) DIDO was increasing over time (with a mean time of 145 mins). Following the introduction of e-Stroke the average DIDO initially reduced by ~75 min, the

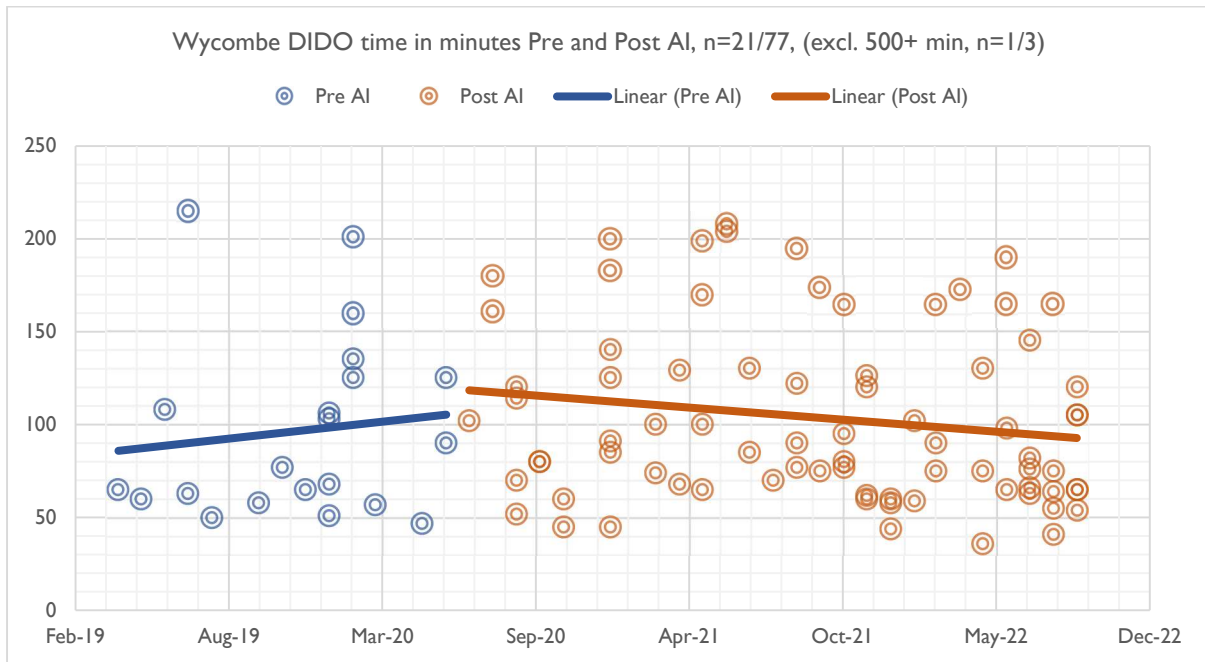
upward trend is still observed but at a slower rate, the mean DIDO post-implementation has reduced to 90 minutes.

We know, from our mid-term survey, that the team at The Royal Berkshire use e-Stroke for all cases. Usage data also indicates that this site requests more CTAs than other sites in this network.



We know, from our pathway mapping exercise, that this site operates a 24/7 service with access to stroke professionals out of hours. They also automatically request CT and CTA scans for all suspected ischaemic stroke patients. We can therefore deduce that improvements in the DIDO times for this site have been facilitated by the introduction of e-Stroke.

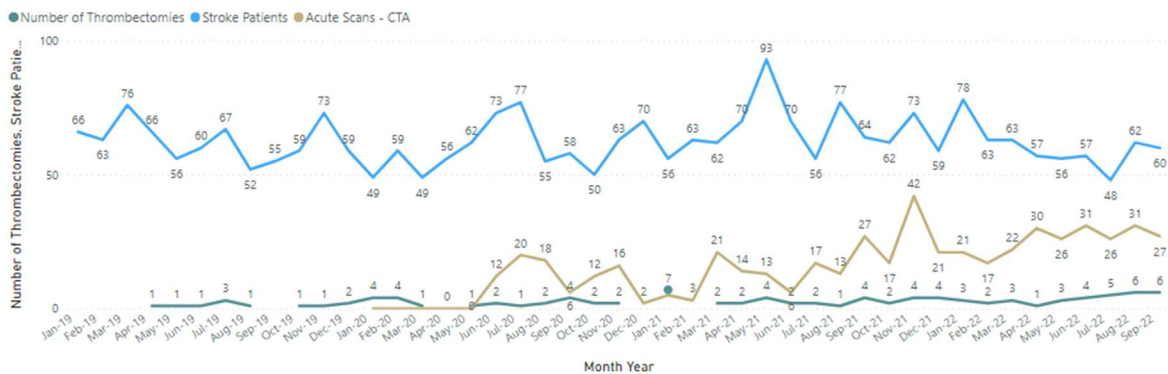
Wycombe



Before the implementation of e-Stroke (Apr 19 to Jun 20) DIDO times at Wycombe were gradually getting worse (increasing over time) with an average time of 97 minutes. Post implementation we have observed a reversal of the trend which is now showing a steady improvement (decreasing over time). The actual post implementation average DIDO is slightly worse than previously seen (104 mins) but should the trend continue, we would expect to see an improvement overall in the next quarter.

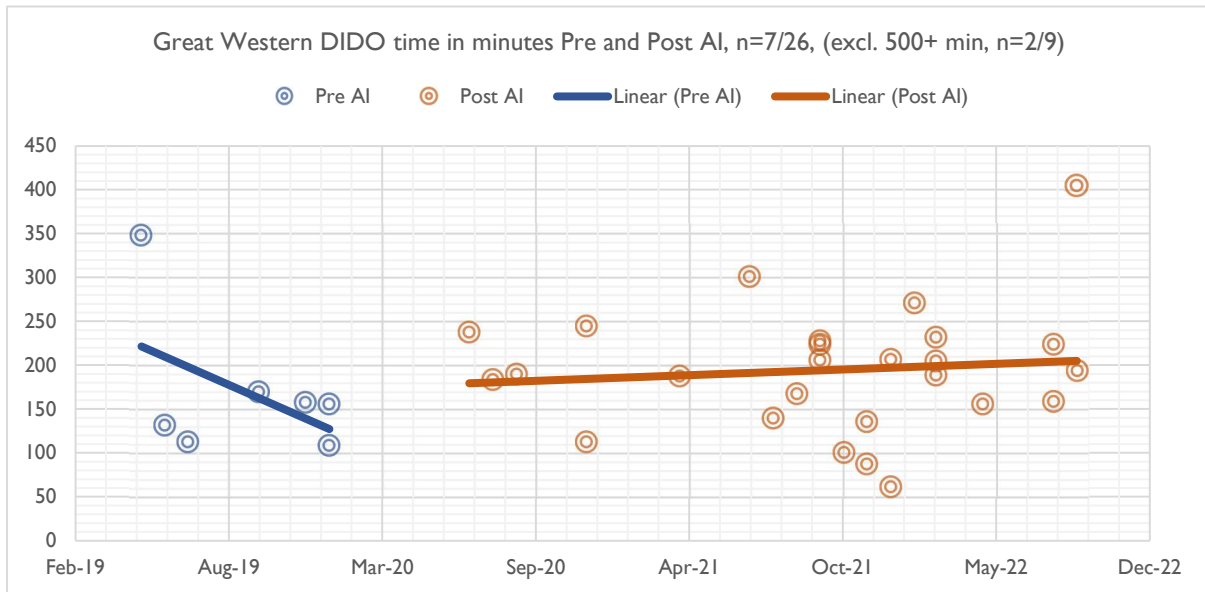
We know that the Buckinghamshire Healthcare Trust at Wycombe have carried out DIDO audits and have as a result, implemented a variety of quality improvement measures and standard operating procedure supporting the hospital's aims to keep DIDO times under an hour with significant improvements made through automatic triggering of CTA scans in thrombectomy candidates. This is reflected in the e-Stroke usage data (below), which shows a steady increase in the number of CTA scans processed by the technology.

Number of Thrombectomies, Stroke Patients and Acute Scans - CTA by Month Year



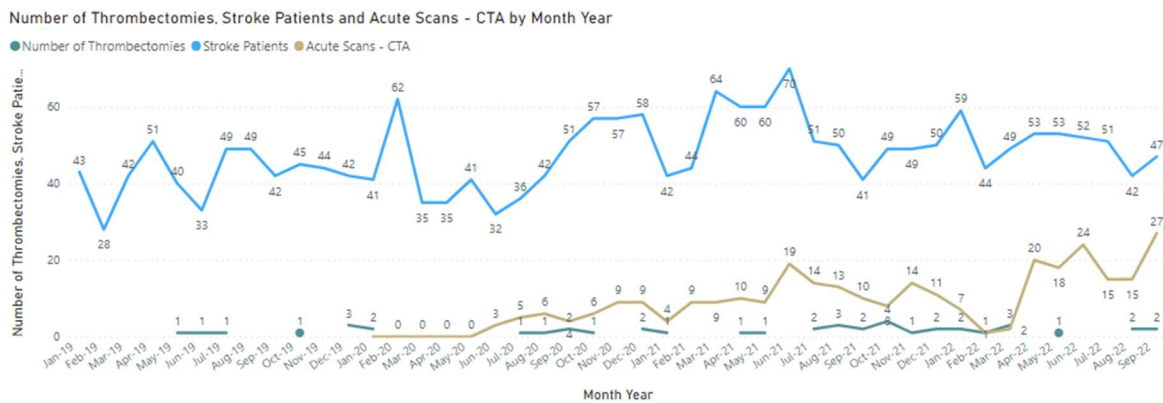
We know, from our pathway mapping exercise, that this site has good access to stroke professionals 24/7. They also automatically request CT and CTA scans for all suspected ischaemic stroke patients, and the increased use of technology would suggest that improvements in the DIDO times for this site have been facilitated by the introduction and sustained use of e-Stroke.

Great Western



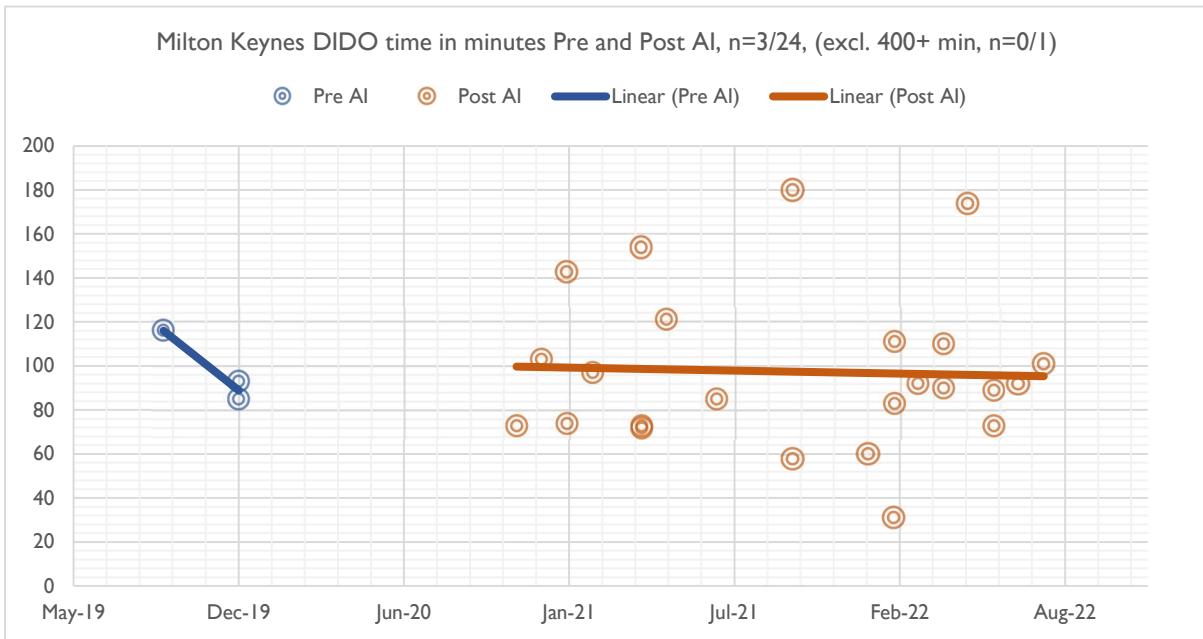
We only have limited DIDO data (n=7) pre e-Stroke implementation but have plotted this above for information. Caution must be given to the interpretation of such a small sample size. We have slightly more post-implementation data (n=26) which shows an average DIDO of 194 mins with a slightly worsening trend over time.

We know, from our mid-term survey, that the team at Great Western use e-Stroke for more than 75% of cases. The rates of MT in this site have doubled pre/post implementation from 1.1% to 2.5%. Use of technology is increasing over time which may explain this increase.

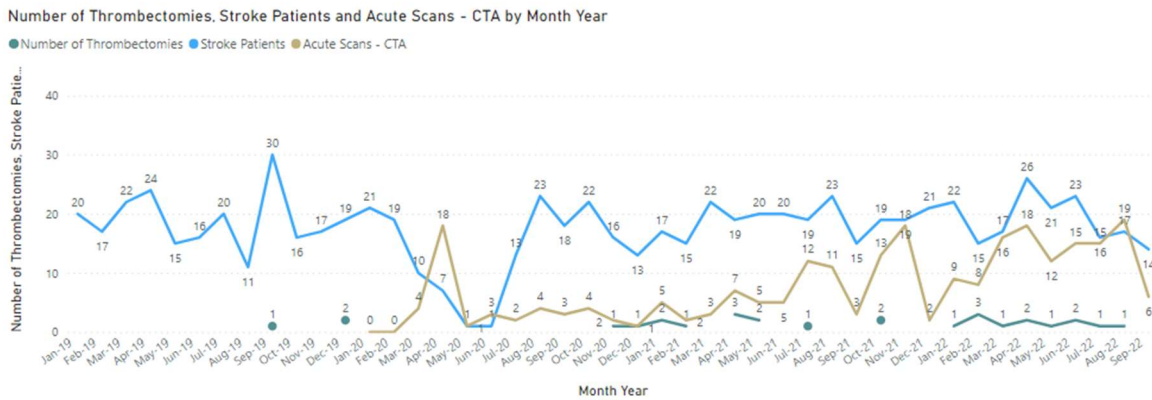


It would appear, from the pathway mapping exercise, that Great Western exclude potential stroke mimics and other conditions before sending for CT and CTA requested at the same time if indicated, whereas other sites in this network go straight to CT. This may be a limiting factor in reducing DIDO for this site, however this is not a new process and was in place pre-implementation of e-Stroke but is a limiting factor to the success of the technology. We also know that there is a process in place to bypass the consultant radiologist should a CTA scan be required and they are not available to approve the request, which would speed up decision time.

Milton Keynes

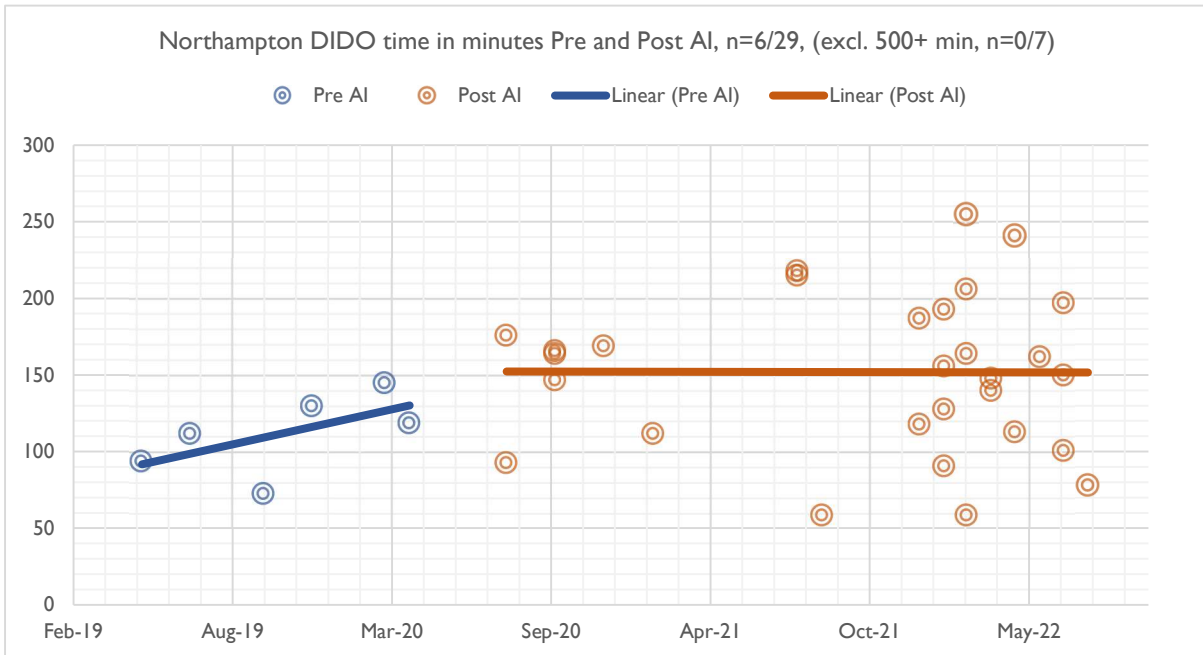


We have very limited DIDO data pre implementation (n=3), however, post-implementation (n=24) we observed a small reduction in DIDO over time with an average time of 97 mins. This site has increased rates of MT by nearly 4% from 1.09% to 4.93%.



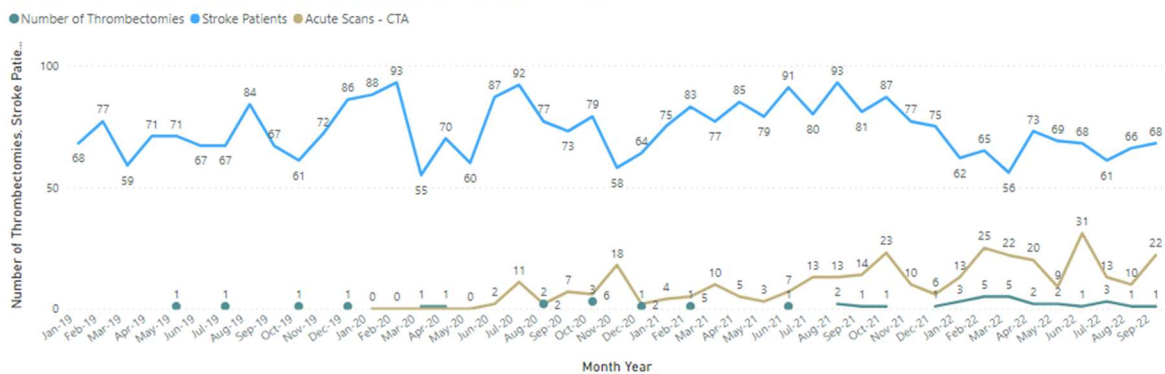
Pre-alerts are in place at this hospital, but only for CT scans. CTA is only requested if a patient is eligible for thrombolysis which we know from other sites can have a significant impact on the DIDO. The decision to request CT and CTA at the same time could show further improvements to the DIDO time at this site. This site is known to ask for advice from stroke physicians at the CSC and they have suggested in their responses to our mid-term survey that if they were a 24 hour service they might use e-Stroke more.

Northampton

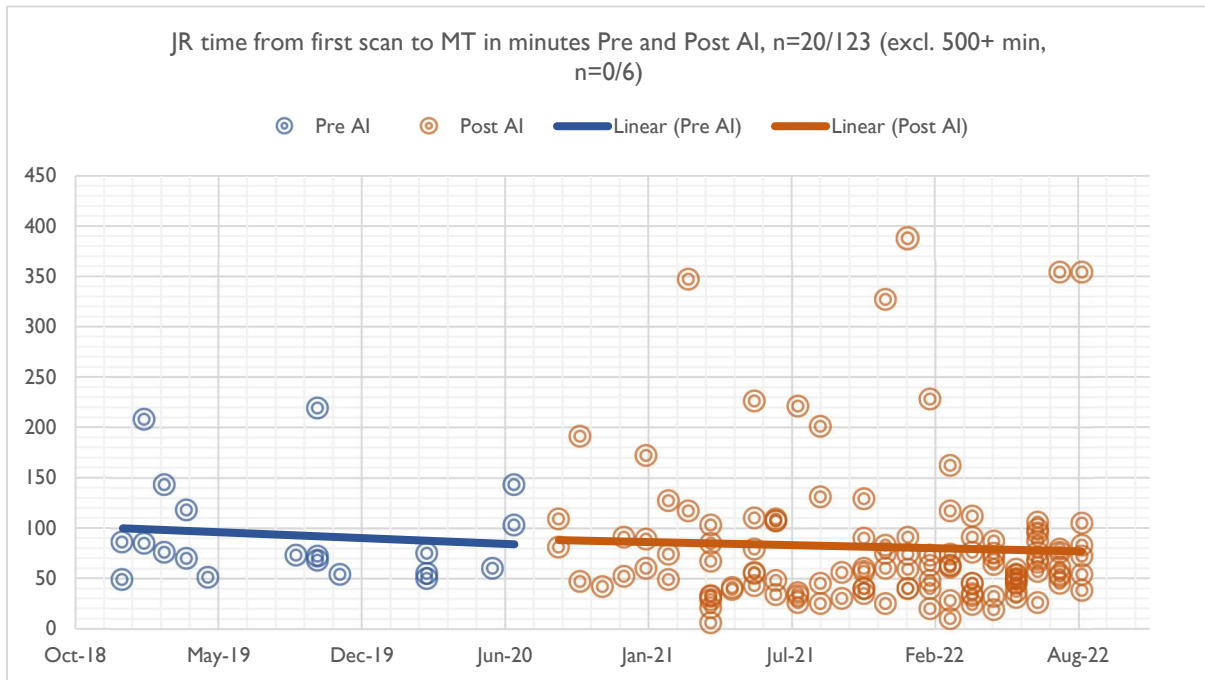


Mean rate of MT has increased 3 fold pre/post implementation from 0.41% to 1.46%, if we look at rates for Jan-Sept 22 they have increased to 3.9%. There is limited DIDO data pre implementation (n=6). DIDO rates appear to remain consistent post implementation (mean time 152 mins). MT rates increasing in line with use of technology. We don't have a survey response from this site, but we know from pathway mapping that CTAs are requested automatically alongside CT scans. This site has amongst the highest stroke admissions in the country, not including London (third highest in the evaluation), very high for spoke.

Number of Thrombectomies, Stroke Patients and Acute Scans - CTA by Month Year



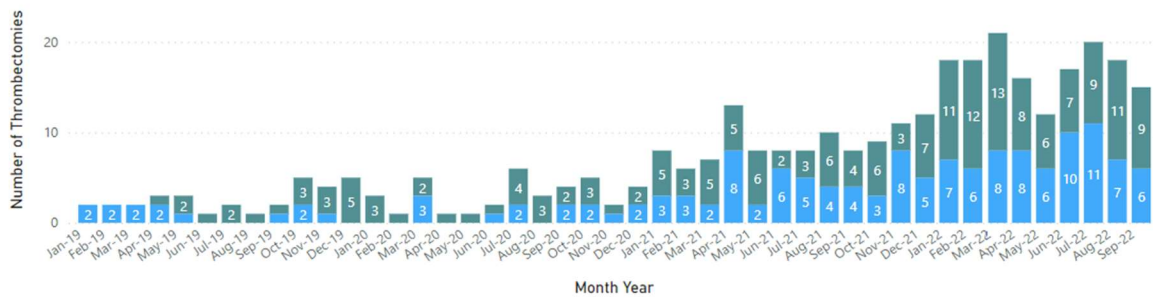
John Radcliffe

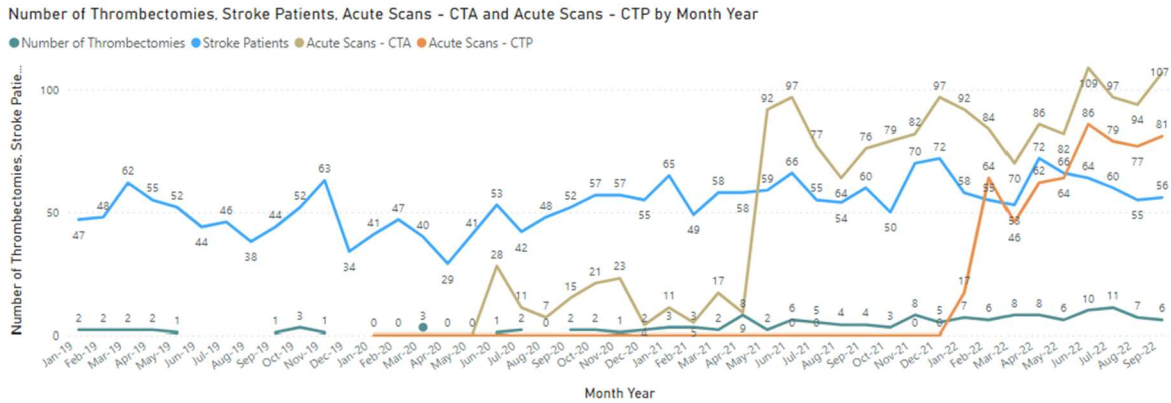


JR has the highest rate of MT in the evaluation, with data from Jan-Sept 2022 showing 12.8%. We also observed that despite a big increase in the amount of MT undertaken that the time from Scan to MT is reducing. This CSC has a fairly even split between patients directly admitted for MT and those that are referred from an ASC (55% referred).

Number of Thrombectomies by Month Year and Is Referred

Is Referred ● No ● Yes

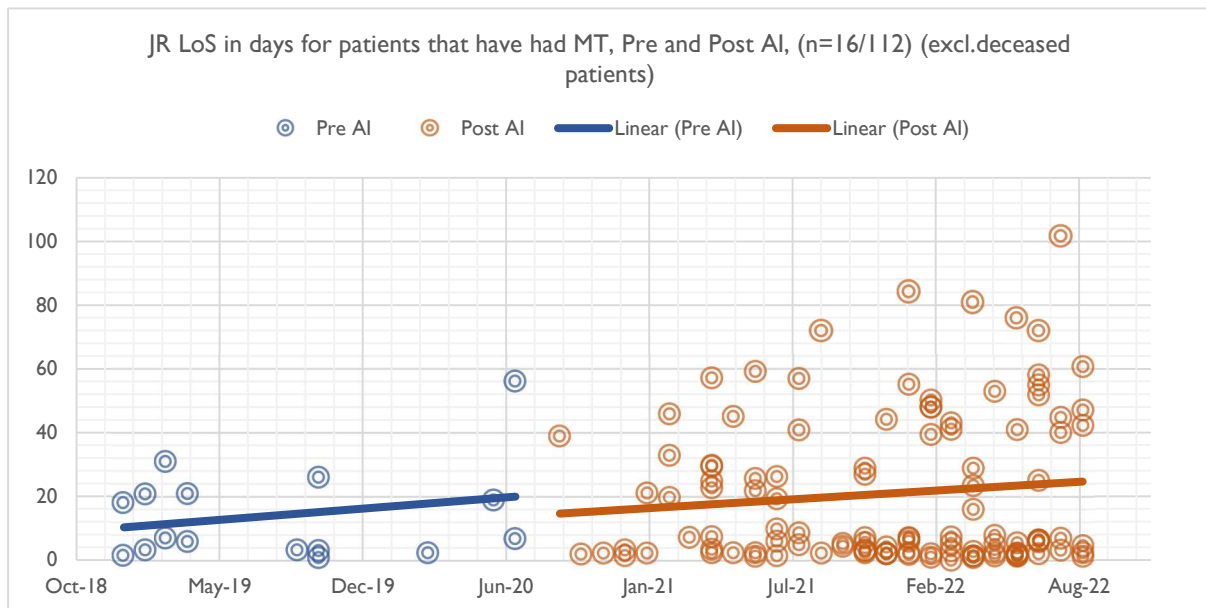




We know, from our mid-term survey, that the team at the John Radcliffe use e-Stroke for more than half of cases on average, with some staff using e-Stroke for all cases. Usage data for this CSC is interesting as there is a significant increase in the numbers of CTA scans processed in May 2021 and we suspect this may be because the Trust decided to automatically process all CTA scans at this point, follow by automatic processing of CTP scans in February 2022.

We know, from our pathway mapping exercise, that the John Radcliffe operates a thrombectomy service 7 days a week. As CT and CTA scans are automatically requested and processed by e-Stroke for all suspected ischaemic stroke patients, along with the increased use of technology we can assume that reductions in the time from scan to MT have been facilitated by the introduction and sustained use of e-Stroke.

Length of stay



This chart shows the length of stay (LoS) in days for MT patients at the John Radcliffe. Deceased patients have been excluded (as otherwise sites with high mortality rates would appear to have shorter LoS).

LoS appears to be increasing gradually with time although there was a small drop immediately after the implementation of e-Stroke.

APPENDIX B – Example from our pre-implementation site aggregate data model, first iteration.

