Greater Manchester Connected Health City (GM CHC)
Stroke Clinical Care Pathway
Work stream 1

Improving recognition of stroke by pre-hospital clinicians (Mimics)

Final report

CLAHRC Greater Manchester

This study/project is supported by the National Institute for Health Research (NIHR) Collaboration for Leadership of Applied Health Research and Care Greater Manchester. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

1. Abstract

Introduction

Acute stroke services are currently centralised in Hyper Acute Stroke Units (HASUs) in Greater Manchester, meaning that when a patient suffers a suspected stroke, ambulance teams should transport the patient to the nearest HASU, and directly to the nearest hospital in all other cases. Despite this, a recent audit by the GM Stroke Operational Delivery Network (ODN) identified that around 48% of patients with suspected strokes via the FAST test and taken to HASUs did not actually result in a stroke diagnosis. These false positive cases are referred to as stroke "mimics" whilst a false negative case was an incident in which a stroke was not recognised using the FAST test. The focus of this workstream was to improve the accurate recognition of stroke cases, reducing the number of stroke mimics and missed strokes.

Methods

Working alongside the Northwest Ambulance Service (NWAS) we first identified how many false positive (mimics) and false negatives (missed strokes) were currently occurring within Greater Manchester. FAST assessment notes were acquired from NWAS Patient Report Forms (PRFs) for analysis. We also introduced the Pre-Hospital Pathway Aid (PHPA) app developed by Greater Manchester Stroke Operational Delivery Network (GM ODN) into ambulance vehicles to help aid stroke recognition. The app was first piloted by 44 NWAS ambulance staff to determine its utility and plan for a wider rollout. A qualitative evaluation was also conducted via focus groups and interviews to explore the decision making of staff involved in the stroke pathway.

Results

A total of 4,148 cases were included in the final cohort data analysis, the PRF diagnoses of whom revealed around 50% were actually experiencing a stroke whilst the other 50% were stroke mimics or false positives. During the piloting period for the PHPA app around 43% of interactions with the app were able to correctly identify a negative FAST test and ensure the appropriate transfer to hospital. As a result the app has been agreed for a full rollout with NWAS, with educational materials being disseminated to all staff in March 2019 ahead of rollout in April. Qualitative findings revealed that respondents were unaware of false positive stroke rates entering onto the stroke pathway. Pre-hospital clinicians receive limited feedback from jobs and this impedes their ability to learn from their experiences. Respondents reported difficulty in ruling out stroke in certain patient cohorts and difficulty in recognising differential diagnoses. They expressed a lack of confidence to rule out stroke in the pre-hospital setting. They also expressed greater concern for 'missed strokes'.

Conclusion

Through analysis of the NWAS PRF data coupled with feedback from qualitative interviews and focus groups, there is a significant issue at present with false positive and false negative diagnosis of stroke in the pre-hospital setting. The successful piloting of the PHPA app has led to a wider rollout that will target the key issues highlighted by this workstream, to reduce the occurrence of incorrect diagnoses

across Greater Manchester, and provide a dataset from which we can develop a model to enhance the current FAST test practices.

2. Introduction

Following the National Stroke Strategy consultation in 2010, acute stroke services were centralised in two regions, 1) London and 2) Greater Manchester and Eastern Cheshire (GM), In these regions acute stroke services are only provided in the designated Hyper Acute Stroke Units (HASUs). This centralisation means ambulance services should only take patients suspected of a stroke to a HASU; in any other cases patients must be taken to the nearest district hospital. The two regions operate different centralisation models; in London all seven HASUs provide service 24/7; whereas in GM HASUs have different service hours, which adds an additional layer of complexity to the decision process undertaken by pre-clinical staff at such a moment.

The *GM Stroke pre-hospital pathway flow chart* (Appendix A) guides pre-hospital clinicians through the GM Stroke Pathway. In addition to the FAST test, this incorporates checks for clinical exclusions that determine if treatment to stabilise a life-threatening situation is to be prioritised over stroke treatment; in which case patients need transferring to the nearest District Hospital A&E unit.

A GM ODN one month audit showed up to 48% FAST positive patients arriving at GM HASUs did not have a final diagnosis of stroke, these cases are referred as false positive cases or *stroke mimics*. As well as diverting resource and time away from true stroke cases at the HASUs, stroke mimics patients with diagnoses such as seizures and sepsis would benefit from faster transfer to the nearest hospital for immediate treatment.

3. Objectives

Working with the NWAS, to link ambulance data with data from Electronic Patient Records (EPR) to identify:

1. Number of cases with a FAST-positive test not given a final diagnosis of stroke (referred sometimes as stroke mimics)
2. Number of cases with a FAST-negative test that were given a final diagnosis of stroke (referred as missed strokes)
3. How cases of stroke mimics or missed strokes arise

Using this information as a foundation, changes will then be implemented and tested iteratively and their impact on the stroke mimics and missed strokes rates monitored. Such changes may, for example, include enhanced pre-hospital clinicians learning through feedback, access to urgent telephone advice or, development of a decision support system.

For this work, we are working closely with the GM ODN, who have developed the Pre-Hospital Pathway Aid (PHPA) app. The app has been designed to support all pre-hospital pathways but initial development and testing has focused on the GM Stroke Pathway. The app reproduces the current pathway (Appendix A) prompting pre-clinical staff to check for exclusions, it identifies the appropriate and nearest service (HASU or general A&E), and prompts pre-alerts to A&E if necessary.

4. Methods

4.1. Qualitative evaluation: Exploring pre-hospital clinicians' decision making in stroke recognition and understanding their views on service improvement initiatives.

Sampling and recruitment

We used opportunistic/snowball sampling methods to recruit 16 pre-hospital clinicians who worked in the GM area of NWAS. Respondents included prehospital clinicians of all grades up to senior paramedic with a length of service ranging from 2 months to over 20 years.

Data collection

Data were collected between August 2017 and December 2017. We conducted:

- 2 focus groups.
- 1 dyad interview (interview with 2 respondents).
- 5 one to one interviews.

Focus groups/interviews were digitally audio recorded and lasted for an average of 72 minutes. Audio recordings were transcribed verbatim.

Data analysis

Data were analysed using a broadly thematic approach and informed by Normalisation Process Theory (NPT) (May & Finch, 2009). NPT aims to understand how novel innovations can be successfully integrated into healthcare settings through four overarching constructs:

- Coherence: can stakeholders make sense of the innovation?
- Cognitive Participation: can stakeholders get others involved?
- Collective Action: what is required to get the innovation to work in practice?
- Reflexive Monitoring: can the innovation be monitored and evaluated?

NPT is most often used to evaluate innovations as they are being, or have been, implemented into practice (McEvoy et al., 2014) given its focus on embedding change into ongoing practice and processes; however, we intended to use it to inform decisions prior to implementation of any service changes. Therefore, we utilised the first two constructs of NPT (coherence and cognitive participation) in the analysis to conceptually explore stakeholder perspectives in detail prior to design.

4.2. Quantitative Methods

4.2.1. Data source and sample size

Initial plans considered analysing electronically recorded data from Salford, Central Manchester and South Manchester HASUs. The proposal was to view this information through DataWell (a data-sharing solution across multiple providers in Greater Manchester), however it emerged Central and South Manchester hospital records did not contain all the information electronically or did not have a node with Datawell. Salford Royal Foundation NHS Trust (SRFT) has a full EPR; therefore sample only contains this population.

FAST assessment notes were obtained from the NWAS Patient Report Forms (PRFs), which are scanned into the patient EPRs. At its time PRF notes were linked to the EPR notes to obtain the final diagnosis and other past medical history details. Case notes were manually reviewed by a Consultant Stroke Physician where discharge diagnosis was not coded. A sample for

retrospective data was obtained, which includes patients coming to SRFT through the Stroke Pathway between 1st September 2015 and 28th February 2017. Only patients brought in by ambulance (BIBA) and who entered the Stroke pathway were included in the sample, all other hospital transfers and duplications were removed from the data in this period.

Data fields of interest from the PRFs were identified and manually extracted by three different CLAHRC staff members, all non-clinical. Guidance to interpret pre-clinical staff notes was provided by ODN staff. The staff member with more experience reviewed approximately a 10% sample for accuracy. Data cleansing was conducted at the end of the data capture period, identifying missing or incorrect fields and correcting as appropriate. The final database was transferred to CHC's Trustworthy Research Environment, all patients personal and sensitive data was removed from the database. Appendix B demonstrates the processes involved in acquiring, accessing, and using the data involved in the Stroke Mimics project.

The PHPA app was piloted by 44 paramedic volunteers from July to September 2017 (17/07/17 and 19/09/17). Pilot data suggested use of the app could improve pathway compliance; 43% of the interactions with the app prompted transport to the nearest hospital for reasons such as a negative FAST test, onset more than 48 hours ago, or the presence of a pathway exclusion. Following the pilot, NWAS has agreed to roll out use of the PHPA app for the Stroke Pathway across GM. Roll out date was agreed for February 2019 but was delayed to March 2019 in order to allow for a promotional educational campaign to ensure full awareness and capability for all relevant staff to use the app. It will not be possible to do a full analysis of the period following the app introduction, but funding for basic data monitoring after implementation in March 2019 and for a period of 6 months has been put in place. It is expected full data analysis will be undertaken as part of a future funding stream. A further qualitative evaluation is planned for after the NWAS roll out of the PHPA app in GM that will explore enablers and barriers to the implementation.

5. Results

5.1. Qualitative evaluation findings: Exploring pre-hospital clinicians' decision making in stroke recognition and understanding their views on service improvement initiatives.

5.1.1. Respondents' professional roles and work practices

The majority of respondents (n=14) worked full time hours in 12-hour shift patterns and all worked a mix of day and night shifts. Respondents were based at different locations across the GM area, which spanned the three HASU locations. Depending on their professional grade, respondents worked as the sole clinician in a rapid response vehicle and/or as part of a two-person ambulance crew. Respondents described how, depending on staffing levels, the skill mix in two person ambulance crews ranged from double EMT crews to one EMT and one paramedic Because NWAS is a large organisation covering the North West of England, respondents sometimes worked in areas that they were not familiar with This brought challenges if crews were not familiar with clinical pathways from areas they did not usually work in. Further findings are presented under the NPT constructs of Coherence and Cognitive Participation below.

5.1.2. Coherence: Pre-hospital clinicians' understanding of the problem

The themes identified under 'coherence' relate to what extent pre-hospital clinicians felt that accurate recognition of stroke was a problem that needed to be addressed. Prior to taking part in the project, no respondents were aware of the false positive stroke rates being conveyed to GM HASUs. Lack of feedback from jobs was stated as a reason for lack of awareness. Furthermore, while pre-hospital clinicians identified a need for more accurate stroke recognition in the pre-hospital setting, greater concern was expressed for false negative strokes and there was a strong sense of 'erring on the side of caution' throughout the data; these themes are explored in more detail below.

5.1.2.1. Understanding and awareness of misidentification was limited by absence of feedback

No formal feedback mechanism existed for the stroke pathway, so respondents did not receive feedback if they conveyed a patient, whose final diagnosis was not stroke, to a GM HASU. However, respondents reported formal feedback mechanisms in place for other clinical pathways and expressed positive views for these, demonstrating buy-in to the idea of learning adaptively from service data in this way. Further support came from the perception that such feedback would provide opportunities for professional development. There was evidence throughout the data that pre-hospital clinicians strive to develop their own informal feedback mechanisms with hospital and/or primary care staff. However, respondents expressed difficulty in receiving informal feedback because, due to their working patterns and geography of the GM area, they did not always return to the same hospital within the same shift.

5.1.2.2. Risk perceptions regarding misidentification

During focus groups/interviews, when respondents became aware of the false positive stroke rates attending GM HASUs, they identified a need for more accurate stroke recognition in the pre-hospital setting. However, throughout the data, respondents generally expressed greater concern for false negative strokes or 'missed' strokes. Since centralisation of stroke services in GM, respondents felt that pre-hospital clinicians were more likely to place patients on the stroke pathway to 'err on the side of caution' because they felt that incorrect conveyance of an acute stroke patient to a district general hospital may result in suboptimal care. This was linked to pre-hospital clinicians' awareness that acute stroke requires time sensitive treatment. Respondents stated that they preferred to be in the 'right place' and be wrong about the patient having a stroke, than risk taking a patient experiencing a stroke to the 'wrong place' as the effects of not treating a stroke in time could be devastating for the patient and their families. Furthermore, conveying false positive stroke patients to a HASU was not perceived by respondents to be detrimental to patient care. Part of this is due to the geography and structure of GM HASUs; whereby respondents felt justified in bypassing local EDs to convey patients to a HASU, as the difference in distance/time between the two was often 'insignificant'. They also considered that if the diagnosis turned out not be a stroke, patients were still in a suitable place (i.e. a fully equipped ED where they could be referred on to other specialties). Erring on the side of caution was also linked to respondents' perception that they were working within a 'risk averse' organisation.

5.1.3. Cognitive Participation: Pre-hospital Clinicians' Perception of Role in Stroke Recognition

Analysis using the Cognitive Participation construct enabled us to consider whether respondents felt that they were the right people to be involved in interventions to improve accurate stroke recognition, and how current procedures impacted their role and relationships with other professionals. Some respondents perceived false stroke rates to be 'inevitable' in their role, suggesting they did not always have the skills or tools within the pre-hospital setting to recognise a false positive stroke from a 'true' stroke. However, respondents were eager to develop the pre-hospital clinician role and keen to improve their stroke recognition. In addressing this issue, respondents identified changes (i.e. interventions) they felt were required to improve stroke recognition in the pre-hospital setting. These sub-themes are explored in more detail below.

5.1.3.1. Difficulty ruling out stroke in pre-hospital setting

Respondents expressed difficulties in ruling out stroke and making differential diagnoses in the pre-hospital setting. They described acute conditions, which 'mimicked' stroke symptoms; these included conditions such as migraine, Bell's palsy and infection in elderly patients. In discussing the difficulty of recognising differential diagnoses, there was a sense that pre-hospital clinicians lack knowledge and confidence to rule out stroke. This stemmed, in part, from a perceived lack of training in clinical pathways and differential diagnoses. The FAST test was problematic to use with certain cohorts of patients, for example those with co-morbidities, or patients who were intoxicated with alcohol, making accurate stroke recognition more difficult. Respondents felt constrained by the use of the FAST tool, because it did not allow them to use their 'clinical judgement' to rule out stroke. Respondents reported several cases where they had 'no option' but to put patients on the stroke pathway, even when their clinical instinct was to think that the patient was not experiencing a stroke.

5.1.3.2. Feedback and learning

In recognising the need to improve stroke recognition in pre-hospital clinicians, respondents described a number of changes required. There was a tension in the data between respondents who articulated concern about using the same tool to assess stroke as the general public, whilst others (mainly EMT1s) felt that FAST was a useful, simple tool that could be used by all grades of staff. Nevertheless, the majority of respondents identified a need to enhance the 'FAST' test/GM stroke pathway. This included wanting to enhance their current stroke pathway to increase specificity (i.e. to more accurately identify when patients were not experiencing a stroke), but also wanting to make the pathway more sensitive to patients who may present as FAST negative but are experiencing a stroke. The majority of respondents would welcome the creation of a formalised feedback mechanism for stroke cases; however, to enhance professional development, they stated that feedback needed to be timely and constructive. Only one respondent, an EMT1, had concerns that receiving individual feedback could negatively influence future decisions in stroke recognition. There was a sense that pre-hospital clinicians felt 'pushed aside' by HASU staff, with respondents reporting conflict between

them and HASU staff. Respondents expressed a need for greater communication between pre-hospital clinicians and HASU clinicians, which they felt would help them to gain a better understanding of each other's roles and lead to better training opportunities. Furthermore, respondents emphasised that any service changes in the pre-hospital setting were supported by hospital clinicians in secondary care. Suggestions for improving stroke training included student paramedic placements on HASU, organising workshops facilitated by hospital stroke specialists and better utilisation of NWAS's online training platform. Respondents suggested ways in which they could learn from service data, for example, presenting 'case studies' of false positive and false negative stroke cases in NWAS's clinical bulletins.

5.2. Quantitative analysis results

Final Diagnoses

A total of 5,600 cases were included in the data transfer but the final cohort for analysis consisted of 4148 patients. The final diagnosis of each of the patients has been recorded along with the information recorded by the ambulance technicians on the patient record form (PRF). The PRF captures extensive information including stroke specific information such as the FAST test. A table of the demographics of the patients and their final diagnoses is given below, showing that **only around 50% of the patients were actually experiencing a stroke, the rest were mimics**. We can also identify helpful features, for example that the mean age for those experiencing a functional disorder or a migraine was considerably lower than the mean age of the patients experiencing a stroke.

	Total	%	Male	%	Female	%	Mean Age	SD Age
Stroke	2180	52.6	1079	49.5	1097	50.3	73.4	14.4
TIA	482	11.6	228	47.3	253	52.5	70.8	15.2
Epilepsy	242	5.8	124	51.2	118	48.8	68.6	14.4
Migraine	233	5.6	76	32.6	157	67.4	46.8	15.2
Sepsis	215	5.2	101	47.0	114	53.0	75.7	14.4
Bells Palsy	78	1.9	43	55.1	35	44.9	55.3	19.1
Syncope	78	1.9	31	39.7	47	60.3	73.2	15.2
Progressive Symptoms	73	1.8	30	41.1	43	58.9	72.7	17.6
Other Medical Pathology	68	1.6	28	41.2	40	58.8	66.5	17.1
Limb / Facial Pathology	66	1.6	29	43.9	37	56.1	68.3	17.7
Delirium	66	1.6	24	36.4	42	63.6	77.4	14.2
Subarachnoid/Subdural/Epidural Haemorrhage	65	1.6	30	46.2	35	53.8	75.2	13.6
Functional Disorder	57	1.4	19	33.3	38	66.7	48.8	14.7
Hypotension/Hypoxia	55	1.3	23	41.8	32	58.2	75.7	17.0
Intracranial Malignancy	52	1.3	27	51.9	25	48.1	69.1	11.2
Cardiovascular Event	41	1.0	21	51.2	20	48.8	71.8	16.0
Alcohol	25	0.6	13	52.0	12	48.0	55.1	13.0
No Pathology Identified	18	0.4	<15		<15		64.8	18.3
Hypoglycemia	17	0.4	<15		<15		73.5	18.8
Allergy/Adverse Reaction	17	0.4	<15		<15		57.8	20.4
Anxiety Disorder	<15		<15		<15		54.0	14.3
Meningoencephalitis/Mastoiditis	<15		<15		<15		57.2	25.8
All Mimics	1968	47.5	873	44.4	1094	55.6	66.9	18.1

We can break this down further by considering those that were FAST+ and FAST-. We also give the ratio of the number of patients recorded as FAST+ to those that were FAST- to indicate whether

there are mimics, which occur without FAST symptoms that are often believed to be strokes. For example, we can see that migraines and epilepsy often present as FAST+ within the population suspected of a stroke, whereas patients suspected of stroke that actually experience a TIA or delirium are much less likely to be FAST+.

	FAST+	FAST-	Ratio
Stroke	1966	134	14.7
TIA	353	117	3.0
Epilepsy	211	19	11.1
Migraine	207	23	9.0
Sepsis	182	21	8.7
Bells Palsy	70	<15	>4.0
Syncope	61	<15	>4.0
Progressive Symptoms	61	<15	>4.0
Other Medical Pathology	51	<15	>3.0
Limb / Facial Pathology	55	<15	>3.0
Delirium	53	<15	>3.0
Subarachnoid/Subdural/Epidural Haemorrhage	59	<15	>3.0
Functional Disorder	55	<15	>3.0
Hypotension/Hypoxia	47	<15	>3.0
Intracranial Malignancy	52	<15	>3.0
Cardiovascular Event	33	<15	>2.0
Alcohol	23	<15	>1.0
No Pathology Identified	<15	<15	
Hypoglycemia	<15	<15	
Allergy/Adverse Reaction	<15	<15	
Anxiety Disorder	<15	<15	
Meningoencephalitis/Mastoiditis	<15	<15	
All Mimics	1632	264	6.2

If we consider the Stroke pathway exclusions, we can see the number of pathway breaches, where data was available. Note that some variables were missing and therefore these numbers indicate definite breaches within the cohort.

	Stroke	All Mimics
Age.less.than.16	<10	<10
RR.less.than.10	<10	<10
RR.greater.than.30	29	24
BP.less.than.90	19	10
SPO2.less.than.90	14	16
HR.less.than.40	13	10
HR.greater.than.150	10	<10
GCS.less.than.8	18	20
Seizure.activity	26	98
BM.less.than.4	11	14

6. Impact

To deliver high-quality care, it is of paramount importance that the right patients go to the right place at the right time to receive the right care from the right specialists. The 2016 Royal College of Physicians National Clinical Guideline for Stroke[4] states that "Community medical services and ambulance services…should be trained to recognise people with symptoms indicating an acute stroke

as an emergency requiring transfer to a hyperacute stroke centre". The centralised pathway in GM means that patients with a suspected stroke can receive urgent specialist treatment around the clock. However, if non-stroke patients or unstable patients are transferred in error to a HASU, this can be harmful for the non-stroke or unstable patients and can also reduce the time that staff have at the HASU to provide specialist care to stroke patients. Getting the pre-hospital pathway right can improve care for all patients.

The key findings from this project are the large proportion of patients who are incorrectly transferred via ambulance service as a result of a false stroke diagnosis, which may be reduced by the use of the PHPA app developed by the stroke ODN. The piloting period in 2017 demonstrated that 43% of interactions with the app were able to correctly identify a negative FAST test and ensure the appropriate transfer to hospital.

7. Conclusion/Discussion

The successful pilot of the PHPA app with volunteer paramedics has demonstrated the potential for wider implementation of the app itself with the potential to reduce the number of falsely diagnosed strokes across Greater Manchester. Coupled with this, the qualitative findings of the current workstream have demonstrated the importance of supplementing 'big data' (i.e. quantitative data) with 'deep data' (i.e. qualitative data) when developing data driven innovations (Atkins, Kilbourne, & Shulkin, 2017). Data driven learning initiatives, and learning health systems more broadly, can be described as 'sociotechnical' systems (Friedman et al., 2010). The qualitative evaluation has identified that, in developing innovations to improve stroke recognition in the pre-hospital setting, it is crucial to consider pre-hospital clinicians' existing work practices and the organisational culture in which they work.

Clinical and non-clinical staff have identified stroke diagnosis as an issue as well as a general lack of awareness of the occurrence of false positive rates in Greater Manchester. Along with the reported difficulty in ruling out stroke in patients in the pre-hospital setting, a clear need for a tool such as the PHPA app has been demonstrated in practice. The agreements in place with NWAS for full rollout in March 2019 and the funding agreement for a 6-month monitoring period following the app introduction will allow a clear demonstration of the real-life application and success of the PHPA app in tackling the false positive stroke rates, which can then be used to form appropriate applications for future funding based on the workstream.

8. Future plans/sustainability

1) Following rollout of the app, the agreed 6-month monitoring period will demonstrate the utility of the app, the potential for further development and rollout into other locations.
2) To develop an enhanced FAST test, which will have a reduced number of false positives compared to the FAST test for appropriate admissions to the stroke department.
3) This work has been incorporated into the Digital Technologies stream of the Applied Research Collaboration (ARC) programme, which secures funding for the next five years following the completion of the latest CLAHRC programme cycle.

9. References

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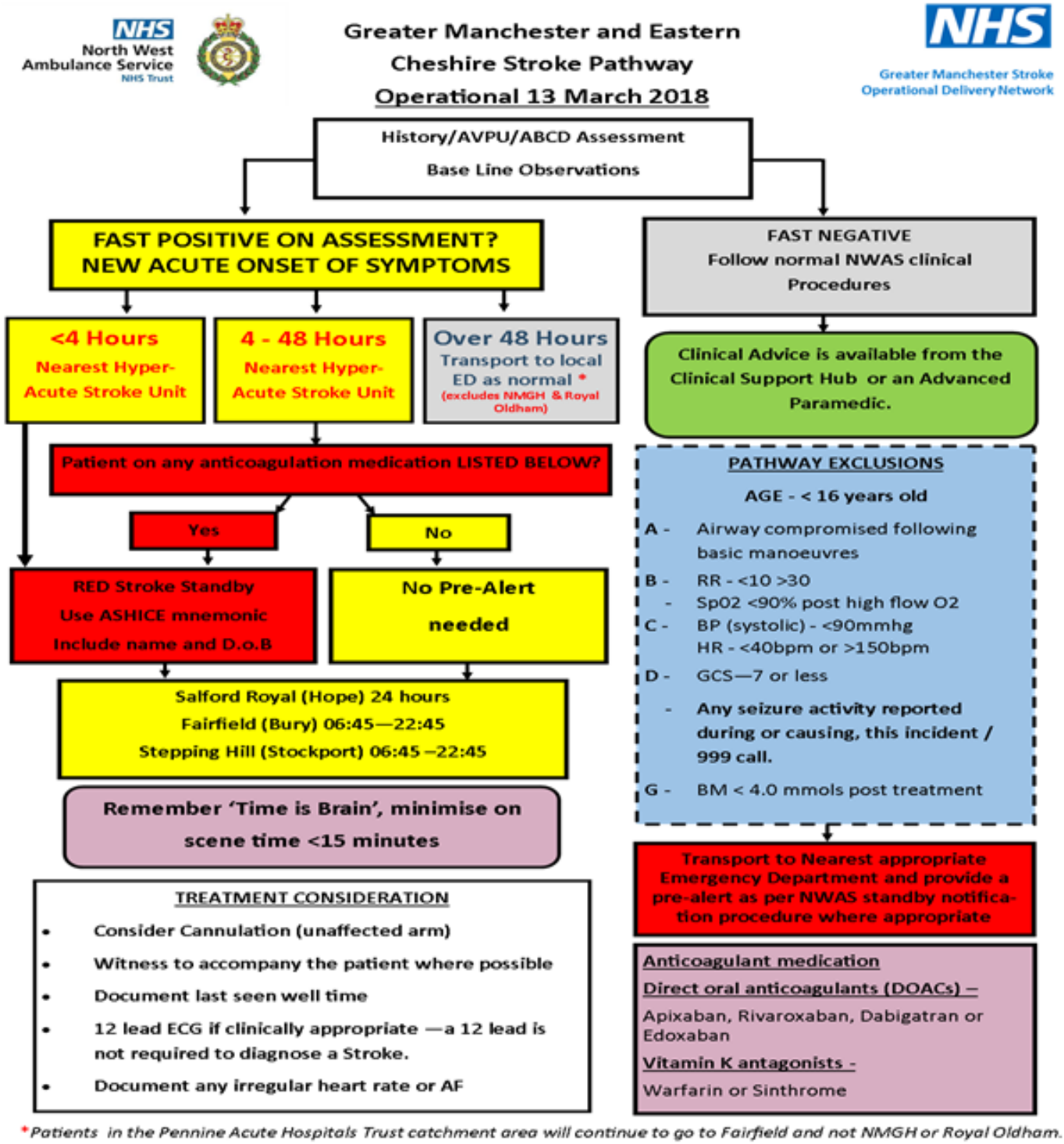
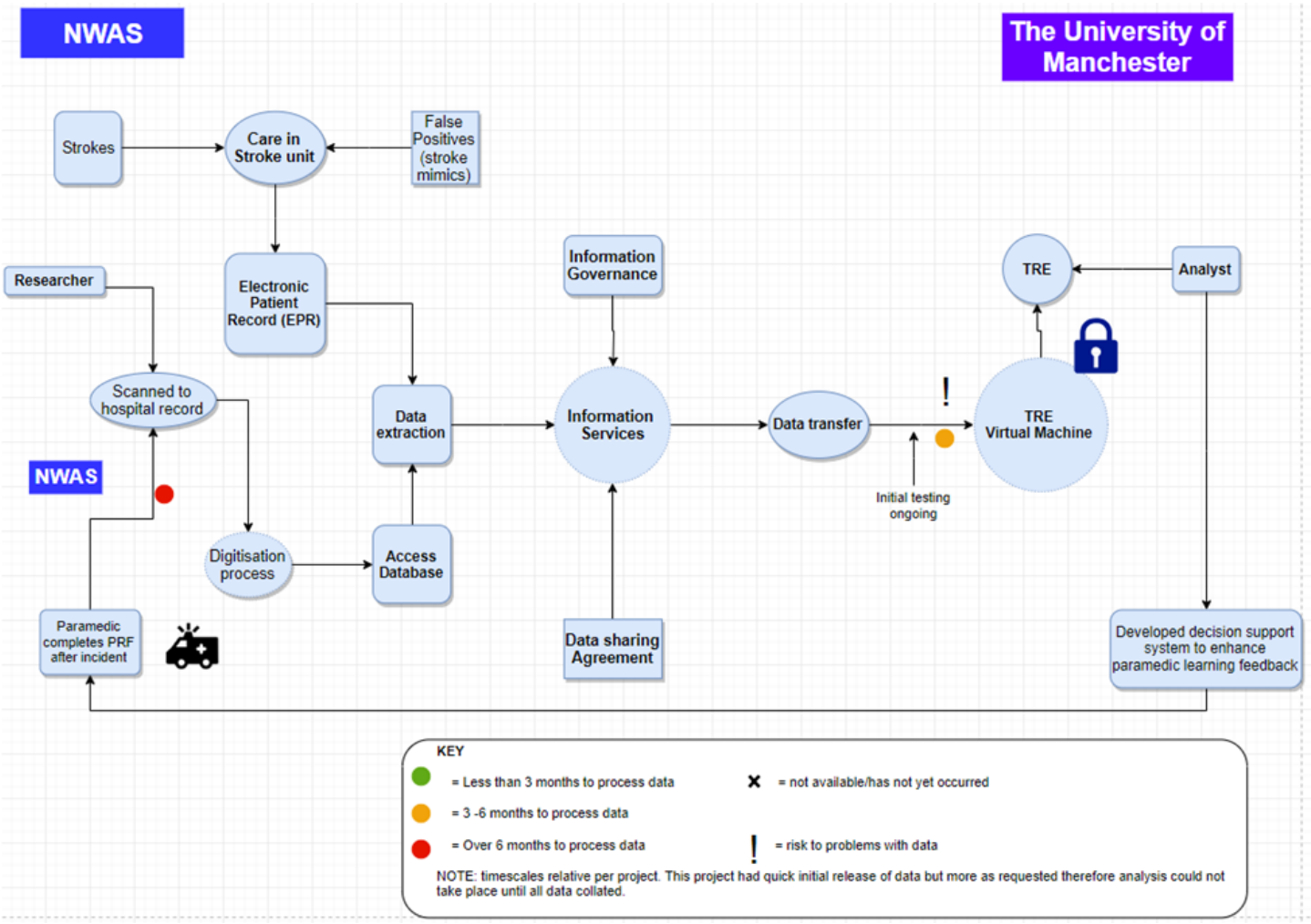
10. Appendices

Appendix A

Greater Manchester and Eastern Cheshire Stroke Pathway



Appendix B



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Produced by Collaboration for Leadership in Applied Health Research and Care (Greater Manchester), April 2019