# Evaluation of reconfigurations of acute stroke services in different regions of England and lessons for implementation: a mixed-methods study

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# **Scientific summary**

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## **Scientific summary**

#### **Background**

Major system change (MSC) involves the reorganisation of services, at the regional level, and may include significant alterations to a care pathway. One such change is service centralisation, whereby aspects of service provision across a region are concentrated in a reduced number of hospitals. The Department of Health and Social Care's National Stroke Strategy for England (Department of Health and Social Care. *National Stroke Strategy*. London: Department of Health and Social Care; 2007) recommended MSC for acute stroke services based on clear evidence of unacceptable variations in quality of care, with many patients denied access to evidence-based clinical interventions. However, evidence on the outcomes of different types of MSC, and the processes and impact of centralising acute stroke services in different contexts, was limited.

We studied efforts to implement MSC in acute stroke services, resulting in 'hub and spoke' systems, consisting of a reduced number of services providing acute stroke care over the first 72 hours following stroke (hubs), with a larger number of services providing care beyond this acute phase (spokes). The service models implemented differed in a number of significant ways.

We compared different models of centralisation, implemented in London and Greater Manchester A (GMA) in 2010.

#### London:

- Eight services were designated as Hyperacute Stroke Units [(HASUs), providing access to hyperacute care, including assessment by specialist stroke teams, brain imaging and thrombolysis, if appropriate] and 24 as Stroke Units [(SUs), providing acute specialist stroke rehabilitation]; five services were decommissioned.
- All stroke patients were eligible for treatment in a HASU.
- All HASUs admitted suspected stroke patients 24 hours a day, 7 days a week (24/7).
- This model remained for the duration of our study.

#### GMA:

- Three hyperacute services one Comprehensive Stroke Centre (CSC) and two Primary Stroke Centres (PSCs) – and 11 District Stroke Centres (DSCs) provided post-4-hour care and ongoing acute rehabilitation services.
- Only stroke patients presenting within 4 hours of developing stroke symptoms were transferred to a CSC/PSC.
- The CSC admitted patients 24/7; PSCs admitted only in-hours (07.00–19.00, Monday–Friday).
- Therefore, the London and GMA pathways differed significantly in terms of eligibility for hyperacute care and uniformity of hyperacute service admission hours.

We subsequently studied further reconfiguration implemented in Greater Manchester B (GMB) in 2015:

- All stroke patients were eligible for treatment in a CSC/PSC (in line with the London model).
- The CSC admitted patients 24/7; PSCs admitted patients 07.00–23.00, 7 days per week.
- These changes brought GMB's service model more in line with the London model.

#### Midlands and East of England:

- The Strategic Health Authority (SHA) commissioned a review of stroke services across nine stroke network areas in 2012.
- Recommendations for MSC were delivered in March 2013.
- By December 2015, no MSCs had been implemented.

#### Our research questions (RQs) were:

- 1. What are the key processes of and factors influencing the development and implementation of the acute stroke service reconfigurations?
- 2. To what extent have system changes delivered process and outcome improvements?
- 3. Have changes delivered improvements that stakeholders (e.g. commissioners, staff, patients, the public and reconfiguration leads) think are worthwhile?
- 4. Have changes delivered value for money?
- 5. How is service reconfiguration influenced by the wider context of major structural change in the NHS?

#### **Methods**

The different models of centralisation implemented in London and Greater Manchester (GM) in 2010 represented a natural experiment. Efforts to implement MSC across the Midlands and East of England and to implement further reconfiguration in GM to a service model closer in line with that of London enabled the study of factors influencing the implementation of MSC during a period of significant structural change. As London's system remained broadly similar throughout the duration of our study, we were able to analyse its long-term sustainability.

To study what works and at what cost, we analysed the impact of changes on clinical outcomes, clinical interventions and cost-effectiveness. To study the development, implementation and sustainability of change, we used qualitative methods drawing on theories related to the dissemination and sustainability of innovations and of MSC.

This was a formative evaluation (i.e. findings were shared throughout the duration of the study to provide lessons for both systems under study and the wider NHS).

#### What works at what cost

We analysed routine data using a controlled before-and-after design, to compare sites pre and post centralisation (in terms of impact of centralisations on clinical outcomes, delivery of clinical interventions and cost-effectiveness), and we made wider comparisons with the rest of England (RoE).

#### Understanding development, implementation and sustainability

We used qualitative methods (documentary analysis, n = 1091; stakeholder interviews, n = 325; and non-participant observations, n = 92;  $\approx 210$  hours) to establish the relationships between activities in support of change, the context, the complex interactions between stakeholders and perceived outcomes of change (including impact on clinical outcomes, delivery of clinical interventions, and patient and carer experience).

#### Synthesis of approaches

We used a mixed-method case study approach to draw together the learning from the approaches described above (London, GMA, GMB, and the Midlands and East of England). We developed a theory-based framework to analyse the relationships between the models selected, the implementation approaches applied, how 'successfully' change was implemented and how these contributed to the impact of change on outcomes.

#### **Results**

#### What works at what cost

The London centralisation performed significantly better than the RoE in terms of mortality [-1.1%, 95% confidence interval (CI) -2.1% to -0.1%; an estimated additional 96 lives saved per year], length of stay (LOS) (-1.4 days, 95% CI -2.3 to -0.5 days) and delivering clinical interventions associated with improved clinical outcomes [e.g. SU within 4 hours: London = 66.3% (95% CI 65.6% to 67.1%); comparator = 54.4% (95% CI 53.6% to 55.1%)]; there was a high probability (72%) that the changes were cost-effective, assuming a willingness to pay (WTP) of £30,000 per quality-adjusted life-year (QALY) (64% probability at £20,000 per QALY, 10 fewer deaths per 1000 patients than in the RoE at 10 years, 58 additional QALYs and at an additional cost of £1,014,363 per 1000 patients), owing to improvements in mortality and morbidity. Analyses of data to March 2016 found that the reductions in mortality and LOS were sustained, and delivery of clinical interventions was either improved or sustained.

Greater Manchester A performed significantly better than the RoE on LOS (–2.0 days, 95% CI –2.8 to –1.2 days), but not on mortality or clinical interventions. GMA CSC/PSCs performed as effectively as HASUs in London, but treated only 39% of stroke patients (whereas 93% of London patients were treated in a HASU); as a result, patients were overall no more likely to receive evidence-based care than patients elsewhere in England. There was a high probability (69% at £30,000 per QALY and 74% at £20,000 per QALY) that these changes were cost-effective, as a result of reduced LOS (6 additional QALYs at 10 years and cost savings of £470,848 per 1000 patients). We reran our models on patients stratified by type of stroke and found that reductions in mortality and LOS were largely achieved among patients diagnosed with ischaemic stroke.

Greater Manchester B performed significantly better than the RoE on LOS (-1.5 days, 95% CI -2.5 to -0.4 days) and clinical interventions (SU within 4 hours: GMB = 79.1%, 95% CI 77.9% to 80.4%; comparator = 53.4%, 95% CI 53.0% to 53.7%) but not on mortality overall (-1.3%, 95% CI -2.7% to 0.01%; p = 0.05), accounting for reductions observed in the RoE. However, there was a significant effect when examining GMB CSC/PSCs only (-1.8%, 95% CI -3.4% to -0.2%), resulting in an estimated additional 68 lives saved per year, with > 80% of patients now treated in CSC/PSCs. At 90 days there was an 88% probability that GMB was cost-effective compared with the RoE over the same time period at a WTP for a QALY of £20,000 and £30,000; at 10 years there was a 31% and 39% probability that GMB was cost-effective at £20,000 and £30,000 per QALY, respectively, although these findings were sensitive to discharge destination, which may have been poorly coded.

Our findings suggest that centralising care provision can offer patients and carers a good experience of care. The opportunity to receive the best-quality care was thought to outweigh the disadvantages of travelling further to receive it. Providing clear, understandable information to patients and their families about every stage of the centralised care pathways maximised their experiences.

#### Development, implementation and sustainability

Both system-wide (top-down) and clinical (bottom-up) leadership were required to enable change. It was necessary to involve a range of stakeholders (beyond physicians) in planning MSC. In London, system-wide leadership was used to co-ordinate multiple local stakeholders to agree to change services and thus overcome resistance to change, and clinical leadership was capitalised on to develop further support for the goals of change. In London, planners were able to 'hold the line' on the service model implemented; in GM, where planners attempted to mitigate potential resistance by making decisions through consensus, the model was changed, implementing a '4-hour model', meaning that the majority of stroke patients would still be treated in their local stroke service rather than a CSC/PSC. Lay involvement was enacted in London and GMA through consultation exercises, lay participation in governance structures and the elicitation of patient perspectives. The value of involvement was found not in its contribution to acute service redesign but in how involvement practices enabled its implementation.

In London, the referral pathway, whereby all patients were eligible for HASUs and all HASUs admitted patients 24/7, was clear and inclusive; it was more likely to be understood and followed by hospital and ambulance staff, maximising the proportion of patients who were treated in a HASU. The single launch date facilitated clear understanding of and adherence to the pathway. Standards were linked to financial incentives; services could not launch until accredited. This increased the likelihood of services providing evidence-based care. These approaches required substantial hands-on facilitation from the local stroke network. In GMA, the referral pathway, where only a selection of patients were eligible for treatment in a CSC/PSC and PSCs admitted patients in-hours only, was less inclusive and more complex than in London. This reduced the proportion of patients treated in a CSC/PSC, in part through limited adherence to the pathway. Phased implementation caused uncertainty among hospital and ambulance staff, both during and post implementation. Service standards were not linked to incentives and there was no accreditation process, which may have led to greater variation across services.

In the Midlands and the East of England (RQs 1 and 5), several factors associated with the successful implementation of MSC were absent or severely hampered. Recommendations drew extensively on data and evidence, but local stakeholders were not sufficiently engaged in the review process, resulting in limited local ownership of recommendations. The programme used lessons from previous changes, but these examples were not engaged with locally because they were felt not to apply (owing to rurality and economic climate). The NHS reforms implemented in 2013 had a significant influence on this programme, including loss of system-wide leadership, making it easier for local commissioners to withdraw support for changes; disrupting system commissioning and governance; introducing significant distraction; and limited time to develop reconfiguration proposals.

In the case of GMB (RQs 1 and 5), turbulence prompted by the 2013 NHS reforms and national staffing shortages led to delays in the agreement and implementation of change; leadership and governance, the use of service and process reviews, and this study's findings on mortality from 2010 changes, were important in enabling implementation. Post implementation, delays in the transfer of patients through the system occurred owing to staff shortages along the whole care pathway. The Operational Delivery Network was a key enabler, facilitating regular audits and system-wide discussions needed to maintain effective system operation.

Sustainability in London (RQs 1 and 5) was achieved despite similar contextual turbulence, namely the 2013 NHS reforms, national targets [e.g. accident and emergency (A&E) targets], staffing shortages and significant pressures on social care services. Resulting pressures on service provision included the delayed transfer of and finding beds for patients. Key promoters of sustainability included service standards linked to the financial incentives, regular service reviews and national audit data, leadership of the model (in terms of continuity and adaptability) and using evidence from our study to ensure ongoing support for the model.

#### **Conclusions**

The analyses of 'what works at what costs' provide evidence that the centralisation of acute stroke services in urban areas can result in significant reductions in mortality and LOS and a significantly higher likelihood of delivering evidence-based clinical interventions. The main limitation of our quantitative analysis was that we were unable to control for stroke severity, meaning that we cannot rule out the possibility that differences in clinical outcomes may be due to variations in stroke severity over time and between regions. The comparisons of London and GMA suggested clear advantages of centralised service models where all stroke patients were eligible for treatment in a HASU; these findings were supported by our subsequent analysis of the impact of GMB. Our study suggests that centralised stroke services can be cost-effective and can offer patients a good experience of care (despite the need to travel further). Our study suggests that service models should ensure that all stroke patients are eligible for treatment in a specialist unit, not just those potentially eligible for thrombolysis.

The analyses of development, implementation and sustainability of the changes provide evidence for other urban areas considering centralising acute stroke services, specifically in relation to (1) issues to consider when selecting a service model (e.g. inclusivity) and (2) processes of implementation (e.g. importance of service standards linked to financial incentives). Although patients and carers had an overall positive experience of services, it is important that clear information is provided at every stage of care.

Although a previous realist review of the literature set out lessons on how MSC might be implemented, little evidence was available in relation to the impact of MSC on outcomes (Best A, Greenhalgh T, Lewis S, Saul JE, Carroll S, Bitz J. Large-system transformation in health care: a realist review. *Milbank Q* 2012;**90**:421–56). By combining a qualitative analysis of processes of change and a quantitative analysis of the impact on clinical outcomes and the delivery of interventions, as well as of cost-effectiveness, we were able to adapt and extend these lessons for MSC. Our research suggests that the following need to be taken into consideration by those planning and implementing MSC more generally:

- Combine bottom-up and top-down leadership, use system-wide authority to align multiple stakeholders
  to overcome resistance to change, and provide continuity of leadership. In the absence of top-down
  leadership, the case of GMB suggests that negotiation across the clinical network, with suitable buy-in
  from commissioners, can drive change successfully.
- Combine feedback with other tools (e.g. the use of audit data and research evidence to build the
  case for change and to assess its impact, and the use of financial incentives to encourage behaviour
  change).
- Acknowledge that implementing lessons learned from previous changes can be hampered by changes in context.
- Involve a range of stakeholders in planning MSC (including but not limited to physicians).
- Understand how a range of factors (e.g. clinical, political, social, financial) influence different stakeholders' views, including potential tension between patients' and others' perspectives.

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