Final report

March 2018

Innovating for Improvement

Delivering an Acute Bundle of Care for Intracerebral Haemorrhage (ABC-ICH): Greater Manchester pilot

Salford Royal NHS Foundation Trust

The Health Foundation

About the project

Project title:

Delivering an Acute Bundle of Care for Intracerebral Haemorrhage (ABC-ICH): Greater Manchester pilot

Lead organisation:

Salford Royal NHS Foundation Trust

Partner organisation(s):

Pennine Acute Hospital NHS Trust

Stockport NHS Foundation Trust

Greater Manchester Stroke Operational Delivery Network

Health e-Research Centre, University of Manchester

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Part 1: Abstract

Bleeding in the brain (intracerebral haemorrhage) causes 1 in 10 strokes. It has a high 30-day case fatality of around 30-40% and over half of survivors remain dependent on others for day-to-day care. There is evidence that reversal of blood thinning drugs, rapid lowering of blood pressure, neurosurgery and care on a high dependency unit can improve outcomes for the right patients.

The aim of our project was to bring about a 10-percentage point reduction in patients dead or severely disabled six months after presenting to a hyperacute stroke unit (HASU) in Greater Manchester between April 2017 and April 2018 with acute intracerebral haemorrhage. We sought to achieve this by implementing our 'ABC care bundle':

Teams at each site identified and addressed local barriers to ABC bundle delivery, secured executive leader and clinician buy in, and planned and delivered launch meetings at their hospitals. HASU teams across Greater Manchester met quarterly for collaborative learning sessions. Marked improvements have been seen in anticoagulant reversal and intensive blood pressure lowering. Quantitative evaluation of the project outcome will be complete by Dec 2018 and process evaluation is currently being finished.

We have developed an app and dashboard for clinicians to facilitate bundle delivery but have met delays due to regulatory requirements. We anticipate introduction at project sites in April/May 2018.

In order to robustly establish the clinical and cost-effectiveness of our bundle during planned scale up, we have applied to the NIHR for funding to conduct a cluster randomised trial.

Part 2: Progress and outcomes

Bleeding in the brain (intracerebral haemorrhage) causes 1 in 10 strokes. It has a high 30-day case fatality of around 30-40% and over half of survivors remain dependent on others for day-to-day care. Until recently, this poor outlook has led to pessimism about intracerebral haemorrhage patients. But there is now evidence that reversal of blood thinning drugs, rapid lowering of blood pressure, neurosurgery and care on a high dependency unit can improve outcomes for the right patients.

The aim of our project was to bring about a 10-percentage point reduction, by April 2018, in the proportion of patients dead or severely disabled six months after presenting to a hyperacute stroke unit (HASU) with acute intracerebral haemorrhage in Greater Manchester. We sought to achieve this by implementing our 'ABC care bundle' for intracerebral haemorrhage:

A – rapid reversal of blood thinning (**A**nticoagulant) drugs.
B – intensive **B**lood pressure lowering.
C - **C**are pathway to ensure timely referral to neurosurgery.

We established a harmonised electronic database at each HASU with a data dictionary and guide to capture all key process measures, baseline demographics, disease severity, and outcomes (death & disability at 6 months). A data lead was established at each site. At Stockport, this was a senior nurse and Bury this was the Sentinel Stroke National Audit Programme data entry lead. To collect 6 months outcomes, we established use of a validated postal questionnaire with telephone follow-up for non-responders. Members of the local care team first perform a survival check and the simplified modified Rankin Scale (mRS: a 7-point composite scale of death and disability) questionnaire is posted with a pre-paid return envelope. Patients may complete and return the questionnaire, await a telephone call (if preferred), or indicate their desire to opt out on the form and return it. Our key process targets are:

1. Anticoagulation reversal:
    i. > 90% of patients eligible to receive anticoagulant reversal receive acute treatment with an appropriate reversal agent.
    ii. > 80% of patients receiving anticoagulant reversal have a door-to-needle time of < 120 min.
2. Intensive blood pressure lowering:
    i. > 90% of patients eligible for intensive blood pressure lowering receive acute parenteral antihypertensives.
    ii. > 80% of patients treated with intensive blood pressure lowering have a door-to-target time of < 120 min.
3. Care pathway for referral to neurosurgery:
    i. > 95% of patients requiring acute referral to neurosurgery are acutely referred.
    ii. < 50% of patients not requiring acute referral to neurosurgery are acutely referred.

The ABC bundle was launched at the two Greater Manchester HASUs (Fairfield General Hospital, Stepping Hill Hospital) in April 2017. Along with Salford Royal NHS Foundation Trust, these HASUs provide acute stroke care to all patients in Greater Manchester, and Salford is the sole provider of Neurosurgery. The project was led at each site by a Stroke Consultant, Senior Stroke Nurse and Data Lead. In the three months prior to launch, teams identified and addressed local barriers to ABC bundle delivery, secured executive leader and clinician buy in, and planned and delivered launch meetings at their hospitals. Teams from the three HASUs meet every quarter for collaborative learning sessions along with the lead Neurosurgeon (Patel). The team at Stockport 'debriefed' staff as soon as possible after each ICH admission to highlight aspects performed well and areads for miprvmeent, a strategy that proved highly effective. We designed and developed a tablet app to be used by acute stroke teams to guide delivery of the care bundle and capture key process data automatically, for display in a linked dashboard. Although the app was developed and finalised by May 2017, complex and unanticipated regulatory barriers have delayed introduction to clinical practice. We expect it to come in to use in the next 1-2 months and discuss the learning from this in Part 4, below.

Despite the app not being available, marked improvements have been seen in anticoagulant reversal (median door-to-needle time: 150 min, interquartile range [IQR] 125 to 400 min before vs. 84 min, IQR 67 to 131 min after; p=0.011) and intensive blood pressure lowering (median door-to-target time: 328 min, IQR 194 to 838 min before vs. 100 min, IQR 75 to 121 min after; p<0.001). Quantitative evaluation of the project will be complete by Dec 2018 as final 6-month outcome data for patients admitted in April 2018 will be collected in October 2018. . However, data are complete for 30-day case fatality at Stockport. A similar magnitude of reduction in case-fatality to that at Salford was seen (30-day case fatality fell from 33.3% (n=72) pre-launch to 23.7% (n=97, 28.8% relative reduction) post-launch. We intend to perform an ordinal regression analysis using 6 month mRS, adjusting for baseline prognostic factorsWe also plan a 'mediation analysis' to begin to explore the contribution each component of the care bundle made to any change in outcomes.

Process evaluation is being conducted alongside this scale up in order to prospectively capture emerging changes in implementation across the three HASUs; to understand how stakeholders and health professionals experience and interact with the bundle; and identify how context might influence implementation across the different sites. Methods include conducting semi-structured interviews with project leads at each HASU (e.g. stroke consultants, senior stroke nurses and data leads) and clinicians (e.g. registrars and nurses) using the bundle at each site; non-participant observation at relevant meetings (including the quarterly collaborative meetings) and analysis of relevant project documents (e.g. site-specific planning documents and protocols). So far (March 2018), 22 interviews and 49.5 hours of non-participant observation have been conducted. Analysis to date has demonstrated how sites may change over time, supporting both the need for continued implementation support to adapt to change, and the need for longitudinal

process evaluation to effectively capture the impact of change. For example, rotation of doctors at the HASUs, alongside high staff turnover impact upon implementation and this has led project leads to consider the need for future re-launch events and to provide multiple, ongoing training opportunities across sites. The evaluation has so far demonstrated how contextual differences at sites impact on implementation. At one site, robust planning prior to implementing the bundle, which included organising a successful launch event attended by the Trust's Chief Executive, was considered to contribute to early adoption of the bundle by clinicians delivering care. By contrast, another site contended with a key project lead leaving the organisation around the time of bundle launch and this contributed to difficulties in implementing the bundle and collecting relevant data in the first three months of its launch.

Part 3: Cost impact

The current annual cost of the stroke service at Salford Royal NHS Foundation Trust is £8,649,334. We expect delivery of our care pathway to lead to a reduction in length of stay for stroke patients. Because patients move between hospitals during acute stroke care (first 2-3 days in a HASU, before transfer to local hospital for remainder of in-patient stay) it is not straightforward to provide a precise reduction in length of stay. We did not have sufficient resource within the project budget to commission a full health economic analysis, but plan this in the next phase of our work (including data from the Sentinel Stroke National Audit Programme, Hospital Episode Statistics and through the use of the EQ-5D-5L at 6 months), for which a funding application is in the late stages of consideration by NIHR Health Services and Delivery Research Board.

A prior study investigating the impact of a more generic pathway without intensive blood pressure lowering and rapid anticoagulation reversal led to a 3.25 days (21.18 to 17.93) reduction in length of stay in China (Deng et al, 2014; Stroke 45: e81-e83). It is likely that the additional evidence-based interventions within our ABC bundle may lead to a greater effect, but we have used this as a conservative estimate of the likely effect. At Salford, we admitted 287 intracerebral haemorrhage patients in the last financial year. A bed on the stroke unit costs £444 per day. We would thus anticipate a reduction in cost of £414,523.

In terms of additional costs associated with the bundle, a detailed analysis of 60 consecutive admissions to Salford with intracerebral haemorrhage concluded that 1 extra admission to Neuro HDU would have resulted if the pathway were applied. A Neuro HDU bed costs £541 per day, so there would be an additional cost of £97 per day for the step up to Neuro HDU. For 41 additional days, this is £3,977 per annum. The cost of anticoagulation reversal and blood pressure lowering are negligible because we are only speeding up a treatment already given for anticoagulation reversal, and the drugs used for blood pressure lowering are inexpensive (e.g. glyceryl trinitrate £15.90 per 50 ml infusion). We thus would anticipate an annual saving of £410,546. Some of this saving would be at the local district stroke centres for the patients admitted from other areas. We would also expect similar savings at the other 2 hyperacute stroke units.

Part 4: Learning from your project

Our aim of implementing the ABC care bundle developed at Salford in two other HASUs in Greater Manchester (Stockport, Pennine Acute) has been achieved. We continue to make improvements in process targets and have learnt a great deal to inform our proposed next phase of work – a pilot cluster randomised controlled trial, described in part 5. Implementation at Stockport was particularly successful, through a combination of a very well-motivated and 'bought in' team with sufficient seniority to drive change, support from the hospital Chief Executive, and a good baseline understanding of quality improvement. Conditions were more challenging at Pennine Acute, with a key member of staff leaving early in the project (a Stroke Nurse Consultant) causing some disruption in the local team. Though she was replaced, it was 3-4 months before the new lead nurse was able to be fully established in post and contribute substantially to the project. This led to some delay, but once the team was fully established, clear improvements have been made to key process targets and data collection established.

Our key learning has been around the development and implementation of an app and dashboard to assist delivery of the care bundle. The app was developed with the m-Health team at the University of Manchester, who have experience in developing apps for academic healthcare projects but had not previously developed an app that was CE-marked. We were aware prior to our application to the Health Foundation that the app would be classified as a medical device and require self-certification with the MHRA (to become CE marked). We rapidly developed the app with the m-Health team, during 2 full 'hack' days with all interested clinicians present to develop a truly clinician-designed app and dashboard. The app and dashboard were complete by May 2017. Whilst the software manufacturer (University of Manchester) has experience of conducting clinical trials of medical devices, self-certification of stand-alone software with the MHRA had not previously been undertaken. There was thus some uncertainly amongst the Research Governance Team about what was required. Once we had met their initial requirements, further documentation and processes were then requested by more senior members of the team, adding a further delay. The University was eventually satisfied with documentation for the app and dashboard and self-certification was then completed in February 2018. The requirements to be met from the University included:

- Adverse event reporting SOP
- Detailed project plan
- Results of clinical evaluation (testing of app on 100 randomly selected retrospective cases)
- Clinical risk assessment

- Essential requirements document
- Formal rationale for device classification
- Summary report of software testing
- Evidence of registration of quality improvement projects with NHS trusts
- Completion of University of Manchester information governance checklist

In introducing the app and dashboard to the NHS Trusts, we have provided the same documentation and have also provide the following:

- Privacy impact assessment
- Data sharing agreement
- Contract between University of Manchester and each NHS trust to cover the loan of equipment (2 Android tablets per trust).

We developed our app in Android as it is easier to eventually place the app on the Google Play Store than the Apple App Store and because the cost of providing tablets is considerably less using the Android platform. We have found since that both trusts use Apple iPads already in the clinical areas. We will thus develop an iOS version of the app for next stages of the work (NIHR application) to allow us to install the app on trust-owned devices, considerably reducing the administrative burden required in introducing the app in the NHS. Our Android tablets are seen as a theoretical risk by NHS trusts as they are 'foreign' devices. We have thus only been granted limited access to trust WiFi or will have access to outside systems (NHS Guest WiFi or a 4G network).

We have also encountered barriers to our app and dashboard because of transfer of data from the NHS trusts to the University of Manchester, where the database used to populate the dashboard is based. We have developed a system where the data are pseudonymised and no patient identifiable data are transferred out of the NHS systems. For future work, we will explore whether the dashboard can be hosted within the N3 (NHS) network which may provide additional reassurance for NHS partners regarding data security.

We anticipate further improvements and consistency in delivery of the care bundle when the app becomes available in June 2018, especially at Bury where implementation has been more challenging. Promotional and training videos have been produced to coincide with app launch which we hope will help to gain buy-in from local clinicians and we are asking local teams to ensure it is used with all ICH cases admitted.

Part 5: Sustainability and spread

We do not know whether the benefit achieved at Salford Royal Hospital by implementing the ABC bundle can be achieved elsewhere, nor do we know if improved survival is at the expense of an increase in severely disabled survivors. An external pilot cluster randomised controlled trial is thus needed to address these uncertainties before proceeding to a definitive trial to robustly evaluate the clinical and cost-effectiveness of our ICH care bundle. We have applied to NIHR Health Services and Delivery Research Board to fund a proposed pilot cluster trial. The outline application was made in August 2018, shortlisted, and a full application submitted in Feb 2018. We expect to hear the final funding decision in June 2018, with a proposed start date of January 2019.

Based on our learning from work in Greater Manchester, we will add careful use of do-not-resuscitate orders as part of the ABC care bundle, making it the 'ABCD' bundle. We will promote careful use of do-not-resuscitate orders in the first 24 hours after patients are admitted with ICH, and not beyond 24 h. A multicentre prospective observational study has tested a policy of avoiding do-not-resuscitate orders in first 5 days of care in a subgroup of patients with severe ICH (defined as GCS score ≤ 12). Based on case mix, 30-day case fatality was predicted to be 50% but was observed to be 20.2%. At 90 days, 27.1% had died, 21.5% had severe disability, 29.9% had moderately severe disability, and a good recovery (mRS 0-3) was achieved by 29.9%. So in this group of severe ICH patients that most clinicians would consider to have a poor prognosis, nearly a third made a good recovery. During our Salford project we found that by taking the approach we propose to replicate for this pilot study, the use of do-not-resuscitate orders within 24 h of admission fell from 33.7% to 22.9%. Formally including careful use of do-not-resuscitate orders in the bundle will help achieve these potential benefits at other sites.

Our application's aim is to test in an external pilot study whether the ABCD hyperacute care bundle can be consistently delivered to patients with acute ICH at other NHS hospitals (based on our learning during the Greater Manchester scale-up) and whether the components and processes of our proposed definitive cluster RCT work together and run smoothly.

Objectives of the pilot study:

1. Determine the feasibility of our proposed trial design and collect pilot outcome data to inform sample size calculations for the definitive trial.

2. Test whether the ABCD bundle can be adhered to consistently and determine which aspects of the implementation strategy and which contextual factors influence delivery.

3. Determine whether an alternative, pragmatic approach to data collection is feasible by piloting an enhanced Sentinel Stroke National Audit Programme

(SSNAP) ICH dataset in parallel with conventional clinical trial data collection.

We will conduct a pilot stepped wedge cluster randomised controlled trial of the ABCD bundle at nine NHS hospitals. NIHR Clinical Research Network staff will recruit 500 patients with acute spontaneous ICH presenting within 24 hours of symptom onset over 12 months. Each cluster will be three hospitals within a region, including the neurosurgical centre. The implementation strategy will include access to our mobile app and dashboard, staff training in improvement techniques, and cluster collaborative learning groups. The concurrent process evaluation will explore the implementation of the bundle, evaluating uptake and fidelity but also local adaptations, and identifying site-specific causal mechanisms or contextual factors. Our quantitative analyses will determine bundle adherence and consistency across sites. Pilot outcome data will inform the sample size for the definitive study. SSNAP data will be compared to clinical trial data for accuracy, completeness and case mix.

Timelines: Following a 6-month set-up period from Jan 2019, a 12-month active recruitment period will commence. A final 6-month period will allow final outcome collection and completion of analyses.

Benefits and potential impact: The ABCD bundle has the potential to improve outcomes for this relatively neglected and severe subtype of stroke whilst reducing the overall cost of care. If the effects found at Salford are replicated nationally, around 1100 lives/year would be saved. This pilot study will provide evidence to inform context-sensitive implementation at scale. If using SSNAP data for cluster randomised controlled trials in UK stroke units is shown to be feasible, this will benefit our definitive trial and the wider stroke research community.