

Connected Health Cities (CHC) Work stream 2

ABC-ICH care bundle

Final report

CLAHRC Greater Manchester

SUPPORTED BY

NIHR | National Institute
for Health Research

1. Abstract

Introduction

The 'ABC' care bundle for intracerebral haemorrhage (ICH) was developed and implemented at Salford Royal Hospital and reduced 30-day case fatality in 2015-2016 by 35%. Implementation of the bundle was scaled out across the two other hyperacute stroke units (HASUs) in Greater Manchester from April 2017. A mixed-methods evaluation was conducted alongside. Support was given to link to datasets across the stroke pathway in GM through the CHC project; an ABC-ICH app and dashboard were developed in collaboration with the m-Health team at the University of Manchester to support implementation and capture process data.

Methods

A harmonised quality improvement register at each HASU captured consecutive ICH patients from 01/10/2016-30/03/2017 (pre-launch) and 01/04/2017-30/03/2018 (post-launch). Quantitative data are presented as median and interquartile range. Qualitative evaluation captured how the bundle was implemented across sites; it involved: 33 interviews with implementation teams/clinicians; 79 hours of non-participant observation; analysis of documents.

Results

Unanticipated regulatory barriers delayed introduction of the app into clinical practice. Despite this, HASU1 significantly reduced anticoagulant reversal door-to-needle time (134 min [120–392; n=14] pre-launch vs 72 min [63–108; n=21] post-launch; $p<0.001$) and intensive BP lowering door-to-target time 336.5 min [199–856, n=22] pre-launch vs 83.5 min [59.5–114.5, n=30] post-launch; $p<0.001$). 30-day case fatality at HASU1 fell from 34.3% (n=70) to 26.8% (n=97, 21.9% relative reduction), but was not statistically significant. No statistically significant changes in care process/ case fatality occurred at HASU2. Qualitative evaluation identified importance of facilitation: all-site quarterly meetings encouraged a learning culture between HASUs; robust planning before bundle launch contributed to early adoption at one site; close monitoring of data helped identify missed targets and provide early feedback to staff. Contextual changes over-time impacted upon implementation across sites, identifying a need for continued implementation support.

Conclusion

Lessons learnt from this project will be used to support an implementation strategy to test bundle in other areas outside of GM and to develop v.2 of the app and dashboard.

2. Introduction

Intracerebral haemorrhage (ICH) is stroke caused by spontaneous bleeding and accounts for approximately 1 in 10 strokes in the UK. Although most strokes are ischemic in nature, caused by blockage of an artery to the brain, ICH accounts for a similar proportion of global deaths (5.8%) as ischemic stroke (6.0%), due to its devastating, 35-40%, early case fatality (GBD 2013 Mortality and Causes of Death Collaborators, 2015). The benefits of primary prevention of ICH (through improved hypertension detection and management) have been offset by the rise in the use of anticoagulation for atrial fibrillation in elderly patients at risk of ICH (Béjot et al., 2013). It is likely, therefore, that ICH will increase as a proportion of total stroke burden. Current Royal College of Physicians Stroke Guideline (Intercollegiate Stroke Working Party, 2016) recommended interventions have been combined in to the 'ABC-ICH bundle'. The bundle consists of:

'A' - *Rapid reversal of Anticoagulation*

'B' - *Optimal delivery of intensive BP lowering*

'C' - *Care pathway to ensure consistent and timely access neurosurgery*

The ABC-ICH bundle was implemented in 2015-16 at Salford Royal Hospital's HASU and 30-day case fatality fell by a third. Compared to pre-implementation, the adjusted odds of death by 30 days were reduced in the implementation period (odds ratio [OR] 0.62; 95% confidence interval [CI] 0.38 to 0.97; $p=0.03$) and this was sustained in the post-implementation period (OR 0.40; 95%CI: 0.24 to 0.61; $p<0.0001$).

2.1. Implementing the ABC-ICH bundle across GM HASUs

Using the learning gained from the development and implementation of the 'ABC-ICH bundle' at Salford Royal, we scaled out implementation of the bundle across the two other GM HASUs (based at Fairfield General Hospital and Stepping Hill Hospital) from April 2017. We aimed to continuously learn from the data through real time monitoring of performance to further improve care.

2.2. Development of ABC-ICH app and dashboard

Support was given to link to datasets across the stroke pathway in GM through the CHC project; an ABC-ICH app and dashboard were developed in collaboration with the m-Health team at the University of Manchester. The app is designed to be used by stroke clinicians and the aim of the app is to facilitate standardised and consistent care, to guide them through the delivery of the ABC-ICH bundle. It simultaneously captures process data for automatic display in a linked dashboard. The data captured in the dashboard can then be reviewed by the internal implementation team (see section 3.1 below) to help identify missed process targets etc., to understand and respond to any challenges they experience with delivering the ABC-ICH bundle of care. Although the app was developed and finalised by May 2017, complex and unanticipated regulatory

barriers delayed introduction to clinical practice. The app was introduced into one GM HASU in August 2018.

2.3. Mixed methods evaluation of scale out of ABC-ICH bundle

We quantitatively evaluated the impact of ABC-ICH bundle implementation across the other two GM HASUs. We evaluated the impact that implementation had on care processes, mortality and functional outcomes at 6 months (see methods section). A qualitative evaluation was also conducted alongside scale out to understand the challenges and successes that occurred in the implementation of the bundle to identify lessons that would guide future (national) scale-out.

The objectives of the qualitative evaluation were to:

- Prospectively capture emerging changes in implementation across the 3 NHS sites (including how continuous learning from the data might influence change).
- Understand how stakeholders and users (health professionals in practice) experience and interact with the 'ABC-ICH bundle'.
- Identify how context (i.e. factors external to 'ABC-ICH bundle') might influence implementation across the different NHS sites.

3. Objectives

3.1. Identifying implementation team at each HASU

A stroke physician, stroke nurse and data lead formed an implementation team at each site. All three HASUs met every three months to share learning and review progress.

3.2. Quantitative Evaluation

Sentinel Stroke National Audit Programme (SSNAP) and ICH registries at each of the three Greater Manchester HASUs were used for evaluation of the bundle implementation. A harmonised ICH audit registry captured consecutive patients with spontaneous ICH at each hospital from 1 Oct 2016 to 30 Mar 2018. Time periods were defined as 'pre-implementation' (1 Oct 2016 to 30 Mar 2017) and 'implementation' (1 Apr 2017 to 30 Mar 2018).

3.2.1. Process and Outcome measures

The following measures were entered into the ICH dashboard at each HASU, by the local data lead, for all patients who were referred to HASU during the time periods defined above:

- Baseline characteristics.
- Clinical presentation.
- Acute care processes (e.g. door to needle time for anticoagulant reversal and door to target time for intensive blood pressure monitoring).
- Imaging characteristics.

The following outcome measures were also evaluated for all patients who were referred to HASU during the time periods defined above:

- 30-day all-cause case fatality.
- 6 month mRS: postal collection using simplified mRS questionnaire with phone follow-up for non-responders.

3.2.2. Statistical analysis

Thirty day case fatality was compared using Kaplan-Meier analysis with logrank test. Process and care measures were compared using the Kruskal-Wallis test. Multivariable logistic and ordinal regression models compared 30-day case fatality and mRS.

3.3. Qualitative Evaluation

Multiple, qualitative methods were undertaken as part of the qualitative evaluation. Data were collected between 22.06.17 to 31.12.18. Purposive sampling and snowball sampling techniques were used to recruit respondents into evaluation.

3.3.1. Semi-structured interviews

A total of 26 respondents took part in 40 semi-structured interviews. Twenty three first interviews were conducted with project leads and clinicians who were implementing the ABC-ICH bundle across the 3 HASUs (n=11 at Salford Royal Hospital; n=5 at Fairfield Hospital; n=7 at Stepping Hill Hospital); a further 10 follow up interviews were conducted approximately one year post implementation with CHC leads and local site project leads (n=3 at Salford Royal Hospital; n=4 at Fairfield Hospital; n=3 at Stepping Hill Hospital). In addition, seven interviews were conducted towards the end of data collection, to discuss App/EPR use across the three HASUs (*note that these interviews were not included in the findings presented but have been used to develop version 2 of the app – see section 5.1 below*). Interviews were conducted by Lisa Brunton, an experienced qualitative researcher. Interviews were digitally audio-recorded and length of interview ranged from 12 minutes (interview terminated due to respondent being called away) to 103 minutes (mean average = 43 minutes).

3.3.2. Non-participant observation

Seventy nine hours of non-participant observation were conducted by LB. Comprehensive (anonymised) notes were handwritten during meetings and written up immediately following observation. Notes consisted of discussions that were had during meetings/events and notes focused on what was said rather than who said what during meetings.

3.3.3. Analysis of relevant project documents

Approximately 40 documents were collected during the data collection period; these included email exchanges prior to bundle launch; SOPs developed for scale out (i.e.

SOP for GM ABC-ICH care pathway and data collection SOP); locally adapted protocols; minutes from quarterly collaborative meetings and local sites' meetings.

3.4. Data Analysis

Data were analysed using a broadly thematic approach which was informed by two implementation science theories: Normalisation Process Theory (NPT) (May et al., 2016) and integrated- Promoting Action on Research Implementation in Health Services (i-PARIHS) (Harvey and Kitson, 2016).

3.4.1. Analysis Process

An iterative approach was taken, whereby data collection and analysis were conducted in parallel. Data were digitally audio recorded and sent to a University of Manchester approved transcription process; once returned they were checked for accuracy by LB. Data was inputted into Nvivo 11: a software package which helps to organise and manage qualitative data. Data were read repeatedly to develop an early coding frame and this was initially informed by Normalisation Process Theory (NPT) – see section 3.4.2 below. Segments of data were coded to the coding frame and extra codes were added as needed. A process of data 'reduction' then occurred – whereby we reduced early codes to broader categories. We also used 'constant comparison' method to further interrogate data to find similarities and differences to test if emerging categories were supported by the data. Further refinement of categories was informed by i-PARIHS framework (see section 3.4.2 below) – this process involved mapping the previous categories (using the broad 4 categories of NPT) onto the i-PARIHS framework.

3.4.2. Theoretical Framework

NPT is a middle range theory (May et al., 2016) which helps us to understand how interventions are (or are not) implemented, embedded and sustained into routine healthcare practice. It has 4 constructs:

- Coherence– relates to whether stakeholders can make sense of the intervention.
- Cognitive participation – relates to whether stakeholders can get other involved in implementing the intervention.
- Collective action – relates to what needs to happen in order that the intervention can work in everyday practice.
- Reflexive monitoring – relates to how the intervention can be monitored and evaluated.

The i-PARIHS framework (Harvey and Kitson, 2016) was used in the later stages of analysis in order to explain the findings from the data; this theory identifies four key factors that drive implementation:

- Facilitation: the process by which facilitators (either external or internal or a combination of both) carry out specific tasks and activities to help others in reaching the implementation goals over time.
- Context: encompasses the micro, meso and macro levels that may act as a barrier to or enabler for implementation.
- Recipients: the role of different people in supporting implementation, at both individual and group level.

- Innovation: users interact with knowledge and evidence as they implement an innovation, which can support or hinder implementation in practice.

3.4.3. Ethical considerations

The qualitative evaluation was reviewed and given ethical approval from the University of Manchester Alliance Manchester Business School Ethics' Panel [Ref: 2017-2078-2946]. Health Research Authority approval was not required as it did not meet their definition of research (classed as service evaluation). We gained governance approval from Research & Development departments at the three NHS sites to carry out data collection. Respondents were provided with written information before taking part and advised that participation was voluntary. All respondents signed a consent form before participating. Transcribed data were anonymised to remove any traceable information, to ensure respondents' confidentiality.

4. Results

4.1. Quantitative Evaluation

One HASU demonstrated marked improvements in care processes, including a reduction in median door-to-needle time for anticoagulant reversal and door-to-target time for intensive blood pressure lowering (Figure 2). This HASU significantly reduced anticoagulant reversal door-to-needle time (134 min [120–392; n=14] pre-launch vs 72 min [63–108; n=21] post-launch; $p<0.001$) and intensive BP lowering door-to-target time 336.5 min [199-856, n=22] pre-launch vs 83.5 min [59.5-114.5, n=30] post-launch; $p<0.001$). The same HASU had a reduction in 30-day case fatality from 34.3% (n=70) to 26.8% (n=97, 21.9% relative reduction), although this was not statistically significant (due to small number of patient cases in the evaluation). Challenges with implementation at the other HASU meant that care processes did not significantly improve and no improvement was seen in 30-day case fatality.

4.2. Qualitative Evaluation

Findings are presented under the four i-PARIHS constructs.

4.2.1. Facilitation

Facilitation was provided by the external team from the site where the bundle had originally been developed and tested, and each site was expected to identify internal facilitators to support local implementation.

- Quarterly collaborative meetings with project staff from all 3 hyper acute stroke units encouraged a culture of learning across sites and created 'healthy competition' to encourage improvements in implementation.
- Robust planning by internal facilitators at one site was considered to contribute to early adoption of the bundle. This involved early identification of

project team, defining project team roles, engaging with relevant clinician groups (pharmacy, haematology, critical care, emergency department leads) to discuss plans and expectations for implementation, organising and advertising a well-attended launch event and training staff in bundle ahead of launch.

- 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. There was less evidence of robust planning at this site, lack of defining team roles and less engagement of relevant clinician groups prior to implementation.
- Close monitoring of data was key to successful implementation: it enabled facilitators to identify when process targets were missed and investigate reasons for this, to inform future delivery of the bundle (and feed this back to staff and re-train staff where necessary). It appeared that close monitoring of data was more likely to occur when Specialist Nurses acted as data leads.

4.2.2. Context

Contextual differences at micro and meso levels impacted upon implementation.

- At one site, successful delivery of the bundle was considered in part to be due to the structural and organisational processes in place; e.g. they have a 3 bedded HASU within their Emergency Department and they have a small dedicated team of 'stroke assessment nurses' who provide acute care to patients in HASU ED. Their nurses were seen as the 'key' to implementing the bundle.
- By contrast, another site struggled throughout the year with staffing issues – this included having a high number of nursing vacancies and a number of locum doctors (who were not necessarily familiar with delivering the bundle). There was a suggestion that, due to staffing issues, the site did not have the time or resources to implement the bundle.
- Rotation of doctors at the HASUs, alongside high staff turnover impacted 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.

Local barriers were identified and the bundle and the processes which support it tailored to fit local context; this contributed to the success of implementation.

- Learning lessons from the development of the bundle at Salford, the other 2 sites developed a protocol so that clinicians no longer required haematology input before administering anti-coagulant reversal agents. This, together with placing a dedicated stock of anti-coagulant reversal agents in their HASU ED bay at one site (to enable immediate access to the drug) led to significant improvements in their anti-coagulant reversal (door to needle times).

4.2.3. Innovation

- The ABC-ICH bundle was perceived as a systematic way to deliver care. It was considered to provide clear guidelines on how to deliver care to a cohort of patients who were perceived to be neglected in comparison to ischemic

stroke patients. Although the components of the bundle are already in national guidance, there did not appear to be a systematic way to deliver care to this cohort of patients until the ABC-ICH bundle was introduced.

- A key factor of the bundle's success appeared to be that the ABC-ICH bundle provided a way to guide the process of care for this cohort of patients. Recipients described a 'culture shift' in clinicians' response to ICH patients: more favourable approach towards ICH patient recovery was noticed.
- There was some concern from recipients that there was a lack of evidence to show that the bundle did not increase disability in surviving patients, but this did not increase resistance to implementation. Implementation teams and recipients at the 2 HASUs considered bundle implementation as a 'quality improvement project' and as one of the measures within this, they collected Modified Rankin Scores (mRS) for patients receiving the bundle, to evaluate if the bundle increased disability in surviving patients. This may have allayed their concerns regarding disability.

4.2.4. Recipients

- As described above, ABC-ICH bundle was generally well received by clinicians in practice
- Problems were identified with Emergency Department staff not adhering to the ABC-ICH bundle; this often occurred when HASUs closed overnight and led to delays in delivering the bundle:
 - Overnight they referred ICH patients directly to neurosurgery instead of the comprehensive stroke centre.
 - ICH was not recognised as 'stroke' by some emergency staff at one site.
 - Patients were kept in the emergency department overnight until stroke staff came back on shift.
- HASU staff continued to make inappropriate referrals to neurosurgery because stroke clinicians lacked confidence to calculate blood volumes; referral to neurosurgery was considered a 'safety net' and was perceived to provide reassurance to families that all options had been considered.

5. Lessons Learnt

5.1. Scaling out implementation of ABC-ICH bundle

The qualitative evaluation identified how facilitation influenced implementation. External facilitation teams need to drive implementation by setting out expectations for internal facilitators, providing role definitions, encouraging ownership of local implementation and providing support in planning.

The ABC bundle was generally acceptable to clinicians but standardisation of how measurement is carried out and data fed back is needed in practice to ensure consistency where a range of clinicians are involved. The evaluation identified the need for continued implementation support to adapt to contextual changes as they occur at local sites. Implementation of the bundle across GM HASUs has shown the importance of longitudinal and cross-site evaluation, to capture not only uptake and fidelity but also

local adaptations to bundle and contextual factors that affect successful implementation.

5.2. Developing and implementing the ABC-ICH app

Another key learning from the project has been around the development and implementation of the ABC-ICH app and dashboard to assist delivery of the ABC-ICH bundle (see appendix 1 for timeline of app development and implementation). The app was developed with the m-Health team at the University of Manchester; they had experience in developing apps for academic healthcare projects, but this was the first time they developed an app that was classified as a medical device and required self-certification with the Medicines and Healthcare Products Regulatory Agency (MHRA), to become CE marked. As reported in section 2.2, the development of the app and dashboard were complete by May 2017 but there was uncertainty amongst the Research Governance Team about what was required for self-certification, so once we had met their initial requirements, further documents and processes were requested by more senior team members, which added to the delay. MHRA self-certification was completed in February 2018. See appendix 2 for a list of documents required for MHRA self-certification and introduction of the app into the NHS Trusts.

Information Governance (IG) permissions were granted in May/June 2018 from the NHS Trusts. Further delays to implementation occurred, as it took some time for IT at each site to organise the following:

- enable the dashboard to be accessed from hospital computers
- enable Wi-Fi access to the tablets
- enable printer access to the tablets

At one site, staff was then trained in the app in June 2018 and the app was being intermittently used from 9th August 2018. Another site has gained relevant permissions but continues to struggle with practical IT issues and the app is still not in use. The app was developed in Android as it is easier to place on Google Play Store than Apple App store and because the cost of providing tablets was considerably less using the Android platform. However, we have since found that both Trusts use Apple iPads. Furthermore, 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 Wi-Fi or will have access to outside systems (NHS Guest Wi-Fi___33 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.

6. Next Steps

6.1. Scale out of ABC-ICH bundle and app outside of GM

Building on work in Greater Manchester, we are currently in discussions with NHS England to support us in launching the bundle (supported by the ABC-ICH app and dashboard) in three other UK regions. A parallel quantitative and qualitative evaluation will determine the impact of the care bundle on death and disability after ICH and ensure the implementation strategy is further optimised for a full national scale up.

6.2. ABC-ICH app and dashboard

The ABC-ICH app is currently being implemented at one HASU in GM and 'demo' tested at another. Based on learning from this pilot launch (and from the 7 interviews conducted with clinicians from the qualitative evaluation), version 2 of the app is currently being developed. We plan to develop an iOS version of the app for next stages of roll out, to allow us to install the app on trust-owned devices, considerably reducing the administrative burden required in introducing the app in the NHS.

7. References

- Béjot, Y., Aboa-Eboulé, C., Durier, J., Giroud, M., Rouaud, O. & Cordonnier, C. (2013). Intracerebral haemorrhage profiles are changing: results from the Dijon population-based study. *Brain*, 136(2), 658-664.
- GBD 2013 Mortality and Causes of Death Collaborators (2015). Global, regional, and national age–sex specific all-cause and cause-specific mortality for 240 causes of death, 1990–2013: a systematic analysis for the Global Burden of Disease Study. *The Lancet*, 385(9963), 117-171.
- Harvey, G. & Kitson, A. (2016). PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. *Implement Sci*, 11, 33.
- Intercollegiate Stroke Working Party (2016). National clinical guideline for stroke, 5th Edition. London.
- May, C. R., Johnson, M. & Finch, T. (2016). Implementation, context and complexity. *Implement Sci*, 11(1), 141.