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Scale-up of ABC care bundle for intracerebral haemorrhage across two hyperacute stroke units in one region in England: a mixed methods evaluation of a quality improvement project

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ABSTRACT

Background Intracerebral haemorrhage (ICH) accounts for 10%–15% of strokes in the UK, but is responsible for half of all annual global stroke deaths. The ABC bundle for ICH was developed and implemented at Salford Royal Hospital, and was associated with a 44% reduction in 30-day case fatality. Implementation of the bundle was scaled out to the other hyperacute stroke units (HASUs) in the region from April 2017. A mixed methods evaluation was conducted alongside to investigate factors influencing implementation of the bundle across new settings, in order to provide lessons for future spread.

Methods A harmonised quality improvement registry at each HASU captured consecutive patients with spontaneous ICH from October 2016 to March 2018 to capture process and outcome measures for preimplementation (October 2016 to March 2017) and implementation (April 2017 to March 2018) time periods. Statistical analyses were performed to determine differences in process measures and outcomes before and during implementation. Multiple qualitative methods (interviews, non-participant observation and project document analysis) captured how the bundle was implemented across the HASUs.

Results HASU1 significantly reduced median anticoagulant reversal door-to-needle time from 132 min (IQR: 117–342) preimplementation to 76 min (64–113.5) after implementation and intensive blood pressure lowering door to target time from 345 min (204–866) preimplementation to 84 min (60–117) after implementation. No statistically significant improvements in process targets were observed at HASU2. No significant change was seen in 30-day mortality at either HASU. Qualitative evaluation identified the importance of facilitation during implementation and identified how contextual changes over time impacted on implementation. This identified the need for continued implementation support.

Conclusion The findings show how the ABC bundle can be successfully implemented into new settings and how challenges can impede implementation. Findings have been used to develop an implementation strategy to support future roll out of the bundle outside the region.

INTRODUCTION

Intracerebral haemorrhage (ICH) accounts for 10%–15% of strokes in the UK[1] and is responsible for half of all annual global stroke deaths and over half of the disability-adjusted life years lost to stroke.[2]

The ABC bundle was developed during a quality improvement (QI) project in 2015–2016 at a large UK hyperacute stroke unit (HASU), from evidence-based interventions recommended in national guidelines.[1 3] Effective delivery of the bundle at Salford Royal Hospital was associated with a 10.8 percentage point (95% CI −17.9 to −3.7; p=0.003) reduction in 30-day case fatality relative to the rest of England and Wales in a difference-in-difference analysis.[4]

Implementation was then scaled up to the other two HASUs in Greater Manchester, UK. This paper reports the mixed methods evaluation that was conducted alongside. Triangulation of data collection and analysis within the evaluation of a QI project enables a thorough investigation of why interventions work or do not work or how they might work[5] and is particularly useful when implementing interventions across different contexts.[6] The need to understand contextual variation, that is, how interventions that work in one setting may not work effectively in another, is now widely recognised to help in the replication and scale-up of interventions.[6 7] We used the integrated—Promoting Action on Research Implementation in Health Services (i-PARIHS) framework[8] to understand the factors that influenced implementation across the two HASUs. This framework identifies four key factors that drive implementation:

1. Facilitation: how facilitators (either external, internal or both) carry out activities to help others in reaching implementation goals over time.
2. Context: encompasses the micro, meso and macro levels of context that may act as a barrier to or enabler for implementation.
3. Innovation: how users interact with knowledge and evidence as they implement an innovation, which can support or hinder implementation in practice.
4. Recipients: the role of different people (both individual and group levels) in supporting implementation.

Our evaluation therefore focused on understanding the challenges and successes when the ABC bundle was implemented across new settings to provide lessons for future spread.

METHODS

Context

Implementation of the ABC bundle took place within a centralised stroke system in Greater Manchester, serving a population of approximately 2.68 million. Acute stroke care is provided via three HASUs; Salford Royal Hospital accepts patients who had an acute stroke 24 hours per day and houses the only Greater Manchester Neurosurgical Centre; Fairfield General Hospital and Stepping Hill Hospital accept patients who had an acute stroke between 06.45 and 22.45 daily and outside of these hours, patients are diverted to Salford Royal Hospital. Hereafter, we refer to sites as Salford Royal and HASUs 1 and 2.

The implementation strategy (intervention and implementation support components outlined below) was developed ahead of launching the bundle at HASUs 1 and 2. It indicates the multiple components, considered necessary to work together, for successful implementation (developed from ARP-J's QI expertise and prior learning from implementing the bundle at Salford Royal).

Intervention

The ABC bundle

The ABC bundle comprises the following process targets[4]:

1. Rapid anticoagulant reversal with delivery of four-factor prothrombin complex concentrate for vitamin K antagonists and anti-Xa antagonists or idarucizumab for dabigatran, with a door-to-needle time (DNT)<90 min.
2. Delivery of intensive blood pressure lowering to a systolic blood pressure (SBP) target of 130–140 mm Hg, for patients who arrive within 6 hours of onset with an SBP over 150 mm Hg, with a needle-to-target time (NTT: time from the first dose of an intravenous antihypertensive to achieving target SBP<140 mm Hg)<60 min. For patients who arrive more than 6 hours after onset (or where onset is unknown) with an SBP>200 mm Hg, we aimed for an SBP<180 mm Hg with an NTT<60 min.
3. Adherence to a care pathway, which prompts immediate neurosurgical referral of all patients with good premorbid function (modified Rankin Scale (mRS) score<3) and any of the following: Glasgow Coma Scale (GCS)<9; posterior fossa ICH; an obstructed third/fourth ventricle; haematoma volume>30 mL (measured by the ABC/2 method).[9]

Implementation support components

External facilitators and QI project teams

Scale-up of the ABC bundle project was supported by an external facilitation team from Salford Royal, comprising the two stroke consultants and consultant neurosurgeon who developed and implemented the bundle at Salford and a newly appointed specialist nurse. Stroke clinical directors at HASUs 1 and 2 were contacted in May 2016 by the project lead from Salford and support for the project was secured in principle while seeking funding. Once funding was secured, each HASU was encouraged to form internal QI project teams, comprising a stroke consultant, specialist nurse and data lead. External facilitators met approximately monthly with the HASU teams during the set-up phase of the project. Initially, external facilitators worked with HASU teams to establish data collection, providing a bespoke database and data dictionary to standardise data collection. HASUs were provided with materials to collect 6-month outcomes and collection of 30-day case fatality was established at each HASU. Protocols from Salford were shared with HASUs 1 and 2 and adapted for local use, based on contextual differences and through process mapping. For example, at Salford, anticoagulation reversal was delivered quickly by using a point-of-care device to measure coagulation and thus dose the reversal agents. One HASU already measured coagulation using a point-of-care device, but no such device was available at the other. Therefore, the protocol was adapted to allow reversal of anticoagulation without an immediate coagulation assessment, with dose adjustments made once the laboratory result was available. At Salford, the supply of reversal agents had been from the transfusion laboratory some 5–10 min walk away from the emergency department (ED), adding delays to treatment. Therefore, a supply of reversal agent was kept in ED to avoid this delay. This was not needed at one HASU as the transfusion laboratory was very close to the ED. Because Salford is the only neurosurgical unit in the region, a regional pathway was produced by the external facilitators and was approved in April 2017. Quarterly meetings were organised by the external facilitation team from July 2017 to enable the project teams to come together to review progress and share best practice.

QI workshops

Representatives from the internal project teams and external facilitators also attended QI workshops organised and conducted by an external National Health Service (NHS) improvement science centre based in Salford. These consisted of three 3-day workshops over the course of a year (from 1 June 2017 to 30 May 2018) and focused on improving clinicians' knowledge of improvement

science, taking teams of clinicians from identification of a change idea to the completion of a QI project.

Undelivered implementation support component: ABC-ICH app

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 aims to facilitate standardised and consistent care by guiding them through the delivery of the ABC bundle. It simultaneously captures process data for automatic display in a linked dashboard to allow immediate and simple access to process data. Although the app was developed and finalised by May 2017, complex and unanticipated regulatory barriers delayed introduction to clinical practice. The app was finally introduced into one GM HASU in August 2018 (after the QI project was completed).

Quantitative evaluation

Study population and data source

A harmonised ICH audit registry was established and captured consecutive patients with spontaneous ICH at each HASU during two periods: 'preimplementation' (1 October 2016 to 30 March 2017) and 'implementation' (1 April 2017 to 30 March 2018).

Baseline, process and outcome measures

Demographics, clinical characteristics, baseline imaging features and acute care processes were entered into the registry at each site by the local data lead. Thirty-day all-cause case fatality and 6-month mRS were recorded. For collection of mRS, we posted the simplified mRS questionnaire[10] and undertook phone follow-up for non-responders.

Statistical analyses

Data are shown as median and IQR for continuous data and as frequencies and percentages for categorical data. Thirty-day case fatality was compared using Kaplan-Meier analysis with logrank test. Process measures were compared using the Kruskal-Wallis test for continuous data and the χ^2 test for categorical data. Patients not directly admitted to the stroke or neurosurgical service were excluded from the main analyses of process measures, since they did not receive the ABC bundle. Analyses of baseline characteristics were repeated in the unselected population to determine any potential impacts of excluding these patients.

Patient and public involvement

Patients were involved in the design of the QI project and dissemination. Discussions with ICH survivors has informed our choice of outcome measures; for example, they felt it was important to understand what impact the bundle had on the level of disability in survivors (mRS scores), as most felt that reduction in deaths should not come at the cost of an increase in severely disabled survivors. We also worked with ICH survivors to develop audiovisual materials to publicise and promote the bundle.

Qualitative evaluation

Design

We used multiple qualitative methods to prospectively capture changes in implementation across the HASUs; to understand how clinicians experienced and interacted with the bundle; and to identify how context influenced implementation across sites. Methods included semi-structured interviews, non-participant observation at meetings/events and analysis of relevant project documents. We used purposive sampling techniques to recruit respondents into the study. This involved identifying individuals who had knowledge of the phenomenon under study and inviting them for interview.[11]

Sample and data collection

All data collection took place between 7 June 2017 and 21 December 2018. Twenty-six respondents took part in forty interviews. Twenty-three first interviews were conducted with external facilitators, internal project teams and clinicians across the HASUs; a further ten follow-up interviews were conducted with external facilitators and internal project teams at approximately 1 year post implementation. In addition, towards the end of data collection, we conducted seven interviews for app development across the HASUs.

Seventy-nine hours of non-participant observation were conducted. This included non-participant observation of the three 3-day QI workshops (n=63 hours); four collaborative meetings (n=12 hours) and five local site meetings (n=4 hours). Handwritten notes were taken during observation of meetings and subsequently typed up; these were structured around the data presented and discussions held during the meetings/workshops observed.

We collected 40 project documents during the project, such as email exchanges, PowerPoint presentations from collaborative meetings, standard operating procedures from HASUs and action logs from HASU1 project team meetings.

Analysis

Interviews were digitally audio recorded, transcribed and anonymised. Data were analysed using a thematic approach, and used the i-PARIHS framework.[8]

Data were uploaded to Nvivo 11, a qualitative software package, to aid analysis. Data were analysed by LB to develop an early coding frame and segments of data were coded, adding extra codes as needed. Members of the research team (LB, RB, SEK) undertook a process of data reduction,[12] whereby we reduced early codes into broader categories. We further refined categories into themes, mapping categories onto the i-PARIHS framework. Throughout, we used the 'constant comparison' method[13] to interrogate the data, to find similarities and differences to test if categories/themes were supported by the data.

Ethical considerations

Implementation of the ABC bundle at each HASU was considered service improvement and local approvals at each HASU were obtained to conduct the project. Research ethics approval for the qualitative evaluation was gained from The University of Manchester Ethics Committee (ref: 2017-2078-2946); HRA approval was not required as it did not meet their definition of research, but individual governance approval was gained from participating NHS trusts. Respondents who took part in interviews/attended events where non-participant observation took place were provided with written information before taking part and advised that participation was voluntary. All interview respondents signed a consent form before participating. Interview data were anonymised during the transcription process and project document data were redacted to remove any traceable information and maintain confidentiality.

RESULTS

Quantitative outcome measures

The project began on 2 January 2017. During the first 3 months, teams were established at the participating HASUs and preparations made for launch of the ABC bundle from 1 April 2017. During this 3-month period, the external facilitation team encouraged sites to liaise with relevant external departments (Haematology, Emergency Department, Critical Care), modify local protocols as needed to deliver the bundle, train the relevant members of the stroke team and prepare a launch event for the project. During implementation, sites were encouraged to monitor process data and test changes to improve, and these changes were shared at collaborative meetings.

Baseline characteristics (table 1) were similar before and after implementation at each HASU, with only the age of patients being significantly lower after implementation at HASU1. 30-day mortality did not change after bundle implementation at either HASU (table 1, figure 1). A high proportion (27.6%) of 6-month mRS scores were missing from the preimplementation cohort at HASU2. Combined with the lack of power due to the

Table 1 Baseline characteristics of ICH patients at HASU1 and HASU2 between 1 October 2016 and 30 March 2018

	HASU1			HASU2		
Factor	Before implementation (n=76)	Implementation (n=107)	P value	Before implementation (n=29)	Implementation (n=94)	P value
Age	81 (73–85)	76 (69–83)	0.034	70.0 (63–80)	75.0 (64–84)	0.182
Premorbid mRS (0–2); n(%)	55 (72.4%)	91 (85.0%)	0.078	22 (75.9%)	82 (87.2%)	0.235
Anticoagulant; n(%)	17 (22.4%) Missing: 1	23 (21.5%)	0.995	3 (10.3%)	25 (26.6%)	0.116
Sex (female); n(%)	39 (51.3%)	57 (53.3%)	0.912	13 (44.8%)	48 (51.1%)	0.708
GCS	15 (12–15) Missing: 1	15 (12–15)	0.832	15 (15–15)	15 (13–15)	0.386
Route of arrival; n(%)	Direct 65 (85.5%) Transfer 9 (11.8%) In-patient 2 (2.6%)	Direct 86 (80.4%) Transfer 20 (18.7%) In-patient 1 (0.9%)	0.326	Direct 27 (93.1%) Transfer 2 (6.9%)	Direct 78 (83%) Transfer 16 (17%)	0.295
SBP on admission	159 (143–184) Missing: 3	165 (147–183)	0.583	172 (154–197)	156 (137–180)	0.128
Infratentorial; n(%)	10 (13.2%) Missing: 2	5 (4.7%)	0.065	2 (6.9%) Missing: 3	6 (6.4%)	1.00
IVH; n(%)	22 (28.9%) Missing: 2	34 (31.8%)	0.897	1 (3.4%) Missing: 4	15 (16%)	0.22
ICH volume (mL)	12.1 (3.0–33.6) Missing: 2	15.9 (5.5–44.6)	0.193	12.0 (3.4–30.6)	10.8 (3.6–23.2)	0.663
Death by 30 days	25 (32.9%) Missing: 3	32 (29.9%) Missing: 3	0.746	6 (20.7%)	22 (23.4%)	0.959
mRS at 6 months*	0–1: 15 (19.7%)	0–1: 22 (20.6%)	0.451	0–1: 5 (17.2%)	0: 24 (25.5%)	<0.001
	2–3: 8 (10.5%)	2–3: 15 (14.0%)		2–3: 4 (13.8%)	2–3: 11 (11.7%)	
	4–5: 12 (15.8%)	4–5: 23 (21.5%)		4–5: 5 (17.2%)	4–5: 7 (7.4%)	
	6: 33 (43.4%)	6: 38 (35.5%)		6: 7 (24.1%)	6: 39 (41.5%)	
	Missing: 8 (10.5%)	Missing: 9 (8.4%)		Missing: 8 (27.6%)	Missing: 13 (13.8%)	

*Presented in groups to avoid small counts but p values are calculated according to ungrouped mRS.
GCS, Glasgow Coma Scale; HASU, hyperacute stroke unit; ICH, intracerebral haemorrhage; IVH, intraventricular hemorrhage; mRS, modified Rankin Score; SBP, systolic blood pressure.

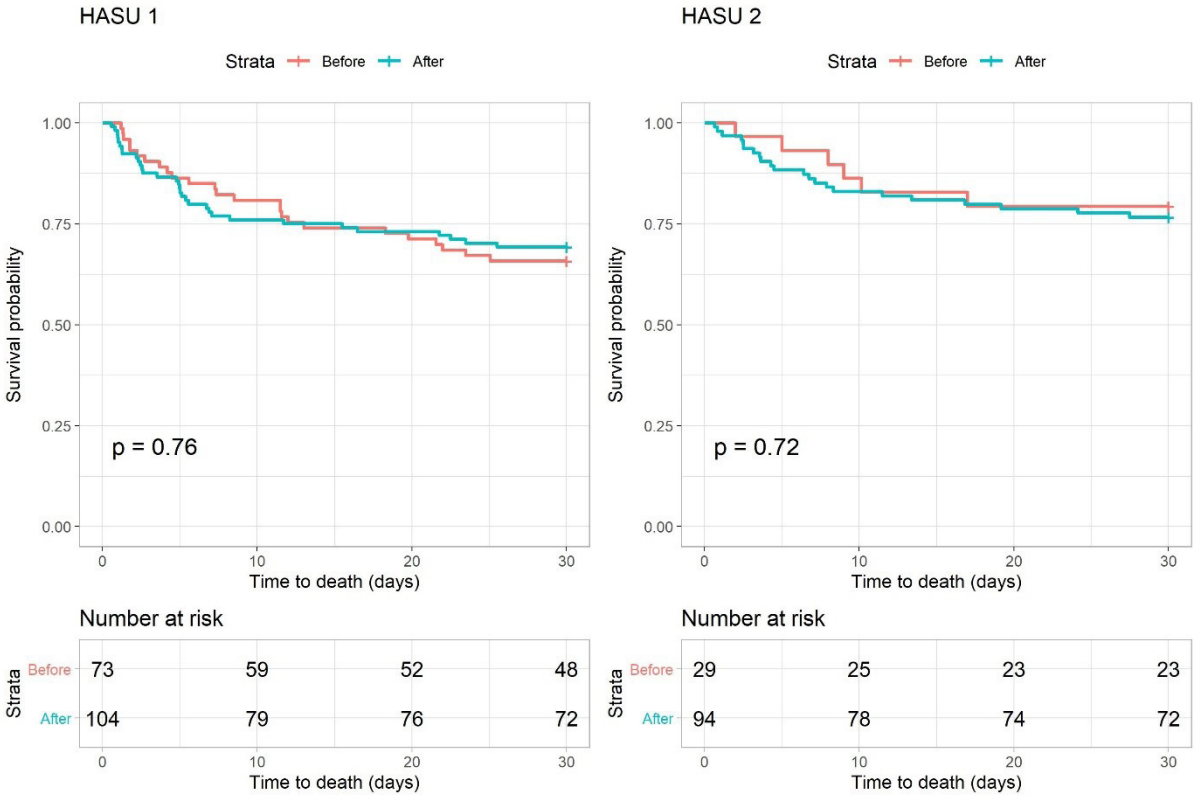

Figure 1 Kaplan-Meier survival curves for hyperacute stroke units (HASUs) 1 and 2. Logrank test was performed to test for any significant difference between those admitted before (red line) and after (blue line) care bundle implementation commenced (1 April 2017).

small number of cases in each group, this prevented a meaningful statistical analysis to compare 6-month mRS before and after implementation. No further differences were observed when evaluating the unselected population (see online supplemental table S1 and figure S1).

We compared process measures before and after bundle implementation at each HASU (table 2). HASU1 halved the DNT for anticoagulant reversal and dramatically improved the DTT for BP lowering. HASU2 reduced the time for anticoagulant reversal, but this was not statistically significant. The proportion of eligible patients who received intravenous antihypertensives doubled at HASU2 to 80.6% (p=0.04), but the NTT did not improve. A significant reduction in referrals made to neurosurgery without an indication was observed, but still the majority of such patients continued to be referred. No significant reductions in the mean SBP nor its variability were seen over the first 72 hours of admission. Only one patient at HASU1 and no patients at HASU2 were admitted to high-dependency care unit or intensive care unit throughout the course of the project. No change was observed in the use of early (<24 hour) do-not-resuscitate (DNR) orders.

Qualitative findings

We present the qualitative findings under the four constructs of the i-PARIHS framework. Online supplemental file 2 provides verbatim quotes and data from observation notes/project document analysis to supplement our findings. HASU1 provides a case of successful implementation, allowing us to identify how facilitating factors supported adoption and adherence to the bundle in the new site. HASU2, which encountered challenges, enables us to see how and where barriers occurred. Together, this comparison enabled us to identify optimal ways of working for successful implementation.

Facilitation

Robust planning by the internal project team at HASU1 was considered to contribute to early adoption of the ABC bundle at their site. This involved early identification of the project team, defining project team roles, engaging with relevant clinician groups (pharmacy, haematology, critical care, ED leads) to discuss plans and expectations for implementation, organising and advertising a well-attended launch event and training staff in the care bundle ahead of launch.

By contrast, HASU2 experienced a key project lead leaving the organisation around the time of the care bundle launch and this contributed to difficulties in implementing the bundle and collecting relevant data in the first 3 months. There was less evidence of robust planning at this site, a lack of team role definition and less engagement of relevant clinician groups prior to implementation. The delay in the introduction of the app was also considered to contribute towards slow implementation of the bundle at HASU2. There was acknowledgement from

Table 2 Process measures reported for ICH patients at HASU1 and HASU2 between 1 October 2016 and 30 March 2018

	HASU1			HASU2		
	Before implementation (n=76)	Implementation (n=107)	P value	Before implementation (n=29)	Implementation (n=94)	P value
Anticoagulant reversal	14/17 (82.4%)	23/23 (100%)	0.137	2/3 (66.7%)	24/25 (96.0%)	0.498
Door-to-needle time (min)	132 (117–342)	76 (64–113.5)	0.006	185.5 (183.2–187.8)	127.5 (74.8–216.3)	0.336
Intravenous antihypertensive (n, number eligible, % of eligible)	24/29 (82.8%)	34/40 (85%)	1.00	4/10 (40.0%)	25/31 (80.6%)	0.04
Door-to-target time (min)	345 (204–866)	84 (60–117)	<0.001	278 (225–333)	425 (225–901)	0.358
Needle-to-target time (min)	243 (139–537)	37 (21–65)	<0.001	270 (210–290)	269 (109–879)	0.867
Mean SBP 0–72 hours (mm Hg)	144.3 (137.3–157.4)	148.3 (134.1–158.3)	0.682	153.3 (131.1–162.6)	146.2 (133.9–160.6)	0.805
SD of SBP 0–72 hours (mm Hg)	17.7 (12.7–23.2)	17.8 (13.5–22.0)	0.858	19.1 (11.9–23.1)	18.2 (13.2–26.9)	0.770
Neurosurgery; (n, referrals made when indicated, % of eligible)	24/27 (88.9%)	41/46 (89.1%)	1.00	10/10 (100%)	26/30 (86.7%)	0.543
Neurosurgery; (n, referrals made when not indicated, % of not eligible)	45/47 (95.7%)	47/61 (77%)	0.015	15/15 (100%)	47/63 (74.6%)	0.067
Neurosurgery; (n, transferred, % of referrals)	3/69 (4.3%)	4/88 (4.5%)	1.00	2/26 (7.7%)	3/74 (4.1%)	0.834
High dependency unit; n (%)	0 (0%)	0 (0%)	NA	0 (0%)	0 (0%)	NA
Intensive care unit; n (%)	0 (0%)	1 (0.9%)	1.00	0 (0%)	0 (0%)	NA
Do-not-resuscitate order<24 hours; n (%)	17 (22.4%)	24 (22.4%)	1.00	5 (17.2%)	18 (19.1%)	1.00

HASU, hyperacute stroke unit; ICH, intracerebral haemorrhage; SBP, systolic blood pressure.

the internal project team that they were waiting for the app to be introduced, expecting this would solve implementation issues they were experiencing.

In addition, HASU1 gained executive support, which included their chief executive attending their launch event. This helped them to navigate governance issues and was considered a source of support when they came up against blocks or delays. Gaining executive buy-in meant that the internal project team was responsible for feeding back progress to their executive team, which was considered to provide another layer of accountability. By contrast, HASU2 did not gain executive buy-in and were not accountable to the executive team, nor gained their help with resources or support.

Close monitoring of data was key to successful implementation at HASU1. This 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). Across the two HASUs, close monitoring of data was more likely to occur when specialist nurses acted as data leads.

Quarterly QI project meetings were held on University premises, so that the internal project teams could take time out of the clinical setting to focus on the project. Data were sent from each internal project team to the external facilitation team ahead of meetings; data were collated by the external facilitation team and presented back to the internal project teams to show each site's success in meeting the process targets. This enabled sites to learn from their own data and learn from each other's experiences. These meetings enabled both internal project teams and external facilitators to identify problems in implementation and work towards overcoming them. The quarterly QI project meetings were considered helpful and created 'healthy competition' between sites and increased collegiality among HASUs. Internal project teams were keen to continue collaborative meetings beyond the QI project.

Context

Contextual differences at all levels impacted on implementation. At HASU1, successful delivery of the bundle was considered in part to be due to the structural and organisational processes they have in place; for example, they have a three-bedded bay used exclusively by the stroke team within their ED and a small, dedicated team of stroke nurses who provide acute care to patients in the ED. These nurses were seen as the 'key' to implementing the bundle. By contrast, HASU2 struggled throughout the year with staffing issues—this included having a high number of nursing vacancies and some locum doctors who were not familiar with delivering the bundle. Internal project teams and clinicians at HASU2 reported that at times, due to staffing issues, the site did not have the resources to implement the bundle.

Local barriers were identified and the bundle and the processes that support it were tailored to fit the local context and this contributed to the success of implementation. For example, rotation of doctors at the HASUs, alongside high staff turnover, impacted on implementation of the ABC bundle and this led internal project teams to provide multiple, ongoing training opportunities across sites and to consider the need for future relaunch events.

In addition, prior to bundle launch and learning lessons from the development of the ABC bundle at Salford, internal project teams at both HASUs developed a protocol so that clinicians no longer required haematology input before administering anticoagulant reversal agents. This, together with placing a dedicated stock of anticoagulant reversal agents in their HASU ED bay at HASU1 (to enable immediate access to the drug), led to significant improvements in their anticoagulant reversal (door-to-needle times).

Innovation

The ABC 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 patients who had an ischaemic stroke. Although 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 at the HASUs until the ABC bundle was introduced.

A key factor of the bundle's success appeared to be that the ABC bundle provided a way to guide the process of care for this cohort of patients. Recipients described a 'culture shift' in clinicians' responses to ICH patients and less nihilism towards ICH patients from clinicians was noticed across all HASUs.

Internal project teams from HASU1 and HASU2 expressed concern that while the ABC bundle may increase survival, there was no data yet on the disability profile of these survivors, but this did not increase resistance to implementation. As part of the 'QI project', HASUs collected mRS scores for patients receiving the care bundle, to evaluate disability in surviving patients, and this appeared to alleviate their concerns.

Recipients

As described above, the ABC bundle was generally well received by clinicians in practice. However, some problems were identified by internal project teams with ED staff not adhering to the ABC bundle protocol; this often occurred when HASUs were closed overnight and led to delays in delivering the bundle. For example, it was identified that ED staff incorrectly referred patients directly to neurosurgery; subsequently, if clinicians were told by neurosurgery to refer the patient to their 'local stroke team' they interpreted this as keeping patients in ED overnight and to refer them to their local HASU in the morning—when the correct procedure would be to refer the patient overnight to the comprehensive stroke centre at Salford.

The A and B part of the bundle implemented more successfully than part C of the bundle at both HASUs; as identified above in the process target measures, clinicians at both HASUs continued to make unnecessary referrals to neurosurgery throughout the year of implementation. Respondents felt this was because stroke clinicians lacked confidence to calculate blood volumes (a necessary step in making the decision to refer patients to neurosurgery), alongside referral being considered a 'safety net' which was perceived to provide reassurance to families that all options had been considered.

In addition, at HASU2, ingrained views regarding the types of patients that critical care would accept for referral had contributed on occasions to stroke clinicians persevering with BP lowering, beyond the time the ABC care bundle protocol suggests to refer to critical care. While some effort was made to improve communication between specialities (eg, a neurosurgeon attended quarterly collaborative meetings) greater communication between HASU, critical care and neurosurgical clinicians was needed to bring about further change.

Reflection on undelivered intervention support component: 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 bundle. The app developers were based in a Higher Education Institute (HEI) and had experience in developing apps for academic healthcare research projects but had not previously developed an app classified as a medical device, requiring self-certification with the Medicines and Healthcare Products Regulatory Agency (MHRA), and intended only for direct clinical care. Although the development of the app and dashboard were complete by May 2017, uncertainty among the host HEI's Research Governance Team about actions required prior to clinical use delayed implementation. Once initial requests were met, further documents and processes were then requested, adding to the delay. MHRA self-certification was eventually completed in February 2018. See online supplemental file 3 for a list of documents that were requested by the HEI for MHRA self-certification and introduction of the app into the NHS Trusts. Information Governance permissions were granted in May/June 2018 from the NHS Trusts. Further delays to implementation occurred, as it took some time for IT departments at each site to enable Wi-Fi and printer access for tablets and enable the dashboard to be accessed from hospital computers.

At HASU2, staff were trained in the app in June 2018 and the app was being intermittently used from 9 Aug 2018, after the QI project had officially ended. HASU1 had gained relevant permissions but continued to struggle with practical IT issues and the app was still not in use at the end of qualitative data collection (December 2018). The app was developed for Android and tablets supplied to each HASU. However, these tablets were seen by NHS IT departments as 'foreign' devices and were thus felt to pose a risk. The app was therefore only granted limited access to trust WiFi or access to outside systems (NHS Guest WiFi or a 4G network). Because the app database was hosted at the HEI, data had to be anonymised, thus limiting clinical use.

DISCUSSION

Implementation of the ABC care bundle at HASU1 was associated with statistically significant improvements in the delivery time of anticoagulant reversal and NTT for intensive BP lowering. Implementation of the ABC care bundle at HASU2 did not result in any significant improvements in reducing delivery times for anticoagulant reversal nor any improvement in NTT for intensive BP lowering, although they improved the proportion of eligible patients receiving intravenous antihypertensive therapy. Although some improvements were seen, both HASUs continued to make inappropriate referrals to neurosurgery, suggesting a continued lack of adherence to the care pathway (C part of the bundle). The qualitative evaluation highlights how intervention effectiveness was dependent on successful implementation.

Good internal facilitation accounted for successful implementation of the A and B part of the bundle at HASU1, with clearly defined roles, individual accountability, regular meetings, early executive team and clinician group engagement, and close monitoring of process data. Internal facilitation at HASU2 was impeded by changes in their personnel leading to less ownership of local implementation and less successful implementation. This highlights how facilitation is a key component of implementation success.[14] The evaluation also highlights how context and contextual differences contributed to implementation. HASU1 had a small team of specialist nurses and a dedicated space in ED to manage patients who had an acute stroke, while HASU2 contended with acute staff shortages over the year of the project. Nevertheless, local adaptions were made to improve process targets at both HASUs, such as developing protocols to bypass haematology input prior to delivering anticoagulant reversal therapy. Similar changes led to similar improvements in process times in an unrelated project at another UK HASU, suggesting that wider spread is feasible.[15]

Multiple, unanticipated barriers were encountered in the development of the app and dashboard, so it was not available for the QI project. A new version has since been developed and key changes include development with a small, private company experienced in implementing IT systems in the NHS for direct clinical care, hosting of the system within the NHS network and development of a cross-platform interface that can be used on any existing device connected to the NHS network.

We identify three key lessons to take forward when scaling up implementation outside of the region:

1. There is a need to set clear expectations for internal project teams; for example, provide them with clear role definitions, encourage ownership of local implementation, and provide support in planning for implementation of the bundle.
2. 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.
3. There is a need for internal project teams to provide continued implementation support to adapt to contextual changes as they occur at local sites.

The absence of a reduction in mortality at HASUs 1 and 2 may reflect the small numbers of ICH patients admitted to the HASUs during the time of the QI project, increasing the likelihood of baseline imbalances and reducing statistical power. The lower mortality figures reported at HASU2 are likely related to case mix, as evidenced by higher GCS scores and lower ICH volumes at HASU2.

An indirect effect of introducing the bundle at Salford Royal was a reduction in early DNR orders,[16] and this was considered to be related to clinicians taking a less nihilistic approach to ICH care. While we did not observe any changes in the use of early DNR orders at either HASU, the qualitative evaluation did capture clinicians' views that implementation of the ABC care bundle had resulted in improved optimism when caring for ICH patients and a sense that they were now treated with the same urgency as patients who had an ischaemic stroke. We did not have sufficient resource to commission a full health economic analysis, but plan this in the next phase of our work.

Limitations

Our overall aim was to understand the facilitators and barriers to spread of the ABC-ICH project and we were not powered to definitively test for improvements in process measures and outcomes. We therefore did not seek to include a contemporaneous control population. This is planned for the North of England scale-up, using data from all stroke units in England, Wales and Northern Ireland not participating in the ABC-ICH project, all of which routinely enter data in to the Sentinel Stroke National Audit Programme (SSNAP).

Additional challenges may be encountered in other regions, such as interaction with a new neurosurgical department and different models of acute stroke care provision. A larger scale-up across the North of England is planned in 2021–2023 and a further process evaluation will capture this. A key outstanding question is whether the ABC care bundle alters disability profile of survivors, increasing the proportion of survivors living with long-term very severe disability. We had insufficient power or completeness of mRS to address this in the Greater Manchester scale-up but aim to address this in our planned North of England scale-up.

From December 2017, SSNAP added questions describing process data for acute ICH care, including anticoagulant reversal and BP lowering. To avoid an additional burden of data collection, we will rely on SSNAP and the ABC app and dashboard for the North of England scale-up, instead of the ICH registry used in Greater Manchester. We anticipate this will improve delivery of the bundle by allowing teams to focus on improvement without the added and often problematic burden of establishing and continuing collection of new data.[17]

CONCLUSIONS

The findings from this study recognise the importance of understanding not just what does or does not work when introducing a bundle of care for ICH into new settings, but how and why, so that ingredients of successful implementation can be identified and communicated to new settings to support delivery at scale. During our planned North of England scale-up, accountability to a regional project lead and early identification of the project team along with written and explicit team roles and expectations may help to facilitate implementation.

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Contributors LB, SEK and RB designed the qualitative evaluation. ARP-J and HCP designed the quality improvement project and quantitative analysis. LB carried out data collection for the qualitative evaluation. EB, CM, SC, NG, KP, OA, AS, KK and ARP-J acquired data for the quantitative analysis. LB, SK and RB undertook analysis of the qualitative evaluation. CS-P undertook statistical data analysis. All authors (LB, CS-P, EB, RB, SEK, CM, SC, NG, KP, OA, HCP, AS, KK and ARP-J) contributed to the interpretation of the data. LB, ARP-J and CS-P wrote the first draft of the manuscript. All authors (LB, C-SP, EB, RB, SEK, CM, SC, NG, KP, OA, HCP, AS, KK and ARP-J) revised the draft critically for important intellectual content. All authors (LB, C-SP, EB, RB, SEK, CM, SC, NG, KP, OA, HCP, AS, KK and ARP-J) have approved the submitted version of the manuscript and have agreed both to be personally accountable for their own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which they were not personally involved, are appropriately investigated, resolved and the resolution documented in the literature. ARP-J is acting as guarantor, accepts full responsibility for the finished work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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