

Implementing a simple care bundle is associated with improved outcomes in a national cohort of ischemic stroke patients.

Melanie Turner, PhD¹; Mark Barber², MD; Hazel Dodds³, BSc; David Murphy³; Martin Dennis⁴, MD; Peter Langhorne⁵, PhD; Mary-Joan Macleod¹, PhD.

Correspondence to Mary-Joan Macleod, Division of Applied Medicine, Department of Medicine and Therapeutics, Polwarth Building, Foresterhill, University of Aberdeen, UK, AB25 2ZD.

m.j.macleod@abdn.ac.uk Tel:00441224437842 Fax:00441224559506

Affiliations:

1. Division of Applied Medicine, University of Aberdeen, Aberdeen, United Kingdom
2. National Health Service, Monklands Hospital, NHS Lanarkshire, United Kingdom.
3. Information Services Division, National Services Scotland, Edinburgh, United Kingdom
4. Centre for Clinical Brain Sciences, University of Edinburgh, Edinburgh, United Kingdom.
5. Institute of Cardiovascular and Medical Sciences, University of Glasgow, Glasgow, United Kingdom.

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Abstract

Background and purpose: Further research is needed to better identify methods of evaluating processes and outcomes of stroke care. We investigated whether achieving four evidence based components of a care bundle in a Scotland-wide ischemic stroke population is associated with 30 day and six month outcomes.

Methods: Using national datasets, we looked at the impact of four standards (stroke unit entry on calendar day of admission (day 0) or day following (day 1), aspirin on day 0 or day 1, scan on day 0, and swallow screen recorded on day 0) on mortality and discharge to usual residence, at 30 days and six months. Data was corrected for the validated six simple variables (SSV), admission year and hospital level random effects.

Results: 36055 patients were included. Achieving stroke unit admission, swallow screen and aspirin standards were associated with reduced 30-day mortality (adjusted OR (95% CI) 0.82 (0.75-0.90), 0.88 (0.77-0.99) and 0.39 (0.35-0.43) respectively). Thirty day all-cause mortality was higher when fewer standards were achieved, from 0 vs 4 (adjusted OR (95% CI) 2.95 (1.91-4.55), to 3 vs 4 (adjusted OR (95% CI) 1.21 (1.09-1.34)). This effect persisted at six months. When less than the full care bundle was achieved, discharge to usual residence was less likely at six months (3 vs 4 standards (adjusted OR (95% CI) 0.91 (0.85–0.98)).

Conclusions: Achieving a care bundle for ischemic stroke is associated with reduced mortality at 30 days and six months and increased likelihood of discharge to usual residence at six months.

Introduction

Health care bundles are a set of evidence-based practices (generally three to five) which aim to help health care providers improve patient care and clinical outcomes¹. Tying these practices together into a bundle with audit of their implementation increases the likelihood that these interventions will be applied in a more consistent manner across and within different hospitals. Some studies suggest that publication of hospital performances towards achieving process standards may improve future patient care², although there are significant challenges in comparing practice in different settings. There is also understandable concern about publishing data which is not robustly corrected for case mix³.

Although specialist stroke unit care is now part of most national guidelines for acute stroke management, further work to dissect out which specific elements of the care process improve outcomes such as mortality or return home is necessary. The Scottish Intercollegiate Guidelines Network produced evidence based guidelines for stroke care in 1997 which in 2004 were incorporated into standards recommended for each stroke patient admitted to hospital in Scotland. Guidelines were updated in 2008⁴ and standards in 2009 (see web appendix I for changes to standards), and include: admission to a stroke unit on calendar day of admission (day 0) or day following (day 1), swallow screen on calendar day 0, aspirin on calendar day 0 or day 1 and brain imaging on calendar day 0⁵. These four standards are monitored nationally by the Scottish Stroke Care Audit (SSCA). Cases are ascertained and data extracted from case notes locally in each hospital by trained audit staff, and entered in a web based database held centrally by Information Services Division (ISD). The SSCA feeds back data to each hospital monthly, and publishes an annual report on stroke care in each acute hospital in Scotland⁶.

Direct comparison of stroke care between institutions is complex due to the variability in data collection, stroke severity, comorbidities and other variables which impact on process and even more so on outcomes⁷. Measures of process may be valuable and reproducible, but will only be clinically relevant if they translate into improvements in clinical outcome. In addition, the factors which influence mortality may be different from those that influence functional recovery, and thus well-defined outcomes need to be evaluated. To increase the validity of data, case mix adjustment is necessary. A recent scientific statement from the ASA highlights that further research is needed to better identify methods and metrics to evaluate outcomes of stroke care³.

The purpose of the current study was to investigate whether the level of compliance with these four evidence based components of a care bundle in a Scotland-wide population admitted with ischemic stroke was associated with better outcomes at 30 days and six months after admission, correcting for known outcome predictors using the six simple variable (SSV) model⁸.

Methods

Data Sources

We obtained data from ISD of NHS National Services Scotland and the General Register Office (GRO) for Scotland.

Information was obtained for all stroke patients admitted between 1st Jan 2005- 15th Sept 2011 at all 36 acute hospitals in Scotland.

The GRO records information relating to all deaths in Scotland. A unique patient identifier, the Community Health Index (CHI) number, allows records from SSCA and the GRO death

registry to be linked. Linkage was carried out by ISD Scotland, then pseudo-anonymised prior to data analysis.

Data Variables

We included all index ischemic stroke events, defined as stroke at final discharge diagnosis. We classified patients as either dead or alive by 30 days and six months after admission or after stroke occurrence if already hospitalised. Recorded discharge destination includes discharged home or to usual place of residence, to another acute hospital, care home, NHS continuing care, an over-riding diagnosis, death, rehabilitation, and other. Deprivation category is calculated according to post code using the Scottish Index of Multiple Deprivation, where one is the least deprived quintile and five the most deprived⁹.

We investigated outcomes for patients achieving each of the standards individually, and according to the number of standards achieved. Main outcome measures were all-cause mortality at 30 days and six months following admission, and the secondary outcomes were stroke mortality at 30 days and six months and discharge to home/usual place of residence at 30 days and six months.

Controlling for bias

Early deaths after stroke may be non-modifiable¹⁰, and may result in the patient dying before they can receive a component of the care bundle. To reduce this potential source of bias, patients who died on days 0 to 3 were removed from the dataset before initial demographic analysis or models were fitted. Patients who were discharged on day 0 were also removed.

Prediction models for long-term outcome after stroke have been developed to adjust for important case-mix variables⁸. We have used the SSV model, which includes age at admission, pre-stroke living arrangement, pre-stroke independence, arm power at admission,

ability to walk at admission, and normal verbal component of the Glasgow Coma Scale (GCS) at admission. These variables are included in the recommended admission data set and relatively simple for trained audit staff to extract from the case notes¹¹. This model performs as well as or better than other simple predictive systems for predicting the outcomes of being alive at 30 days, and independent at six months and one year after stroke⁸. We have previously shown that stroke unit admission is associated with better outcomes up to one year, using the SSV model for case mix adjustment, with a ROC for mortality at 6 months of 0.82 (SE 0.002)¹². A systematic review of case-mix adjustment models for stroke confirms that the SSV model demonstrates statistical robustness, good discriminatory function in external validation studies and comprises variables that are clinically feasible to collect at ward level by non-specialist staff¹³.

Although stroke care in Scotland is generally similar in all acute NHS hospitals, there are differences in service organisation and numbers of admissions, in addition to case mix. We therefore added hospital as an additional variable for adjustment.

Ethics approval

The study was approved by Scotland A Research Ethics Committee, Ref. No.=10/MRE00/76 and the Privacy Advisory Committee of ISD, NHS Scotland, Ref 76/11.

Statistical methods

We performed data management and statistical analyses using SPSS version 22 and SAS version 9.2. Using standard descriptive statistics, characteristics for the study cohort were calculated as percentages for categorical variables and means/medians for continuous variables.

Using multilevel multivariable logistic regression models we firstly investigated outcomes for patients achieving each of the standards individually and then to estimate associations with 30 day and six month mortality. Patients who achieved the full bundle were used as the index group. Adjustment was made with the SSV and year of admission. Age was a continuous variable, while the others were categorical. The model was a two level multivariable logistic model using random intercepts for each hospital to account for the clustered nature of the data. The effect of the care bundle on outcome of discharge to home/usual place of residence at 30 days and six months was also investigated using logistic regression adjusting for the effects of the SSV, year of admission and hospital.

Complete data were available for all outcomes measures. 13.1% had one or more of the case-mix adjustment variables missing and exploratory analysis was carried out to assess missing data patterns. Missing data were randomly distributed between hospitals but commoner in the earlier years of the audit.

In order to assess whether missing case mix variables would affect the results, we performed missing data imputation using Markov chain Monte Carlo (MCMC) method with five iterations. The adjusted ORs with 95% CI for outcomes restricted to the cases with complete case-mix information were more conservative than the results for all cases with imputation of missing data. All estimates were therefore focused on analyses of complete cases.

Results

Patient demographics are presented in Table 1.

Data were available for 36055 patients. The numbers and percentage receiving none, one, two, three and all four components of the bundle are shown in supplemental table I. 2264 (6.3%) patients had a missing value for one or more of the bundle components. Between

2005 and 2011 there was a steady increase in the numbers achieving the full bundle (figure 1). Further adjustments took year of index event into consideration.

Adjusted OR and 95% CI were obtained for complete cases (n=29672). Table 2 shows the frequency of achieving each individual component of the bundle, and adjusted OR for all-cause mortality 30 days and six months after admission. The most commonly attained standard was aspirin started on day 0 or 1 (84.4%), followed by swallow screen (77.4%) and brain scan on day 0 (77.1%). Admission to a stroke unit on day 0 or 1 was only achieved in 58.7%. Admission to a stroke unit on day 0 or 1, swallow screen on day 0, and aspirin on day 0 or 1 were associated with reduced mortality at 30 days.

Patients admitted to a stroke unit on day 0 or 1 were more likely to achieve the other three measured components of the bundle. If patients achieve the stroke unit standard, the OR for achieving the other components of the bundle are: scan on day 0 2.57 (95% CI 2.44-2.71); swallow screen on day 0 3.42 (95% CI 3.24-3.62); aspirin on day 0 or 1 1.46 (95% CI 1.37-1.54).

Table 3 shows mortality according to the number of standards achieved for each patient. There was an incremental decrease in all-cause mortality with more standards achieved at both 30 days and six months after stroke. Where one or more of the bundle components was not recorded, patient mortality was comparable to the group who did not meet any of the standards.

Table 4 shows the adjusted OR for all-cause mortality at 30 days and six months using those meeting the full bundle as the index group. As the number of standards achieved increased, there was a significant reduction in mortality at both time points, compared to the index group.

Supplemental table II shows mortality at 30 days and six months where stroke was the underlying cause of death on the death certificate, according to the number of standards achieved.

Table 5 shows the adjusted OR for the outcomes of discharge to usual residence at 30 days and six months, according to the number of components of the bundle achieved, with the index group being those achieving all components of the bundle. While there was no significant relationship between compliance with standards and discharge to usual residence at 30 days, those who achieved only one component were less likely to return home compared to the index group. At six months, a relationship between numbers achieving the standards and discharge destination was seen, with those who achieved the full bundle more likely to have returned to usual place of residence.

Discussion

Our national study has shown that implementation of a care bundle for ischemic stroke comprising four basic components of clinical care is associated with reduced mortality at 30 days and six months, and with increased likelihood of discharge to usual place of residence at six months. While not all standards individually predicted outcome, the overall bundle contributes to improved patient outcomes of mortality and likelihood of successful discharge to usual place of residence.

Some, but not all, studies have shown that stroke patients who achieve recommended standards of care are more likely to survive. A systematic review⁷ reports that 9 out of 14 studies found an association between positive metric compliance and stroke outcomes, with considerable variation in size and population composition, risk adjustment methods, data capture and time windows for measurement of outcome. A national Danish study of mortality at 30 and 90 days after stroke found an inverse dose response relationship between

the number of quality standards met (early admission, early antiplatelets or anticoagulant, early scanning, early physiotherapist, occupational therapist and nutrition assessment) and mortality at 30 and 90 days. This study did not include functional endpoints such as discharge destination¹⁴.

A study of 36179 hospital patients from English hospitals participating in the Stroke Improvement National Audit Programme and the Sentinel Stroke National Audit Programme also found a relationship between process of care and mortality at 30 days¹⁵. An organisational model and three process measures ((1) seen by consultant or specialty doctor within 24 hours of admission, (2) nutrition screening and formal swallow assessment within 72 hours and (3) antiplatelet therapy and adequate fluid and nutrition) were associated with reduced mortality. Interestingly they too found no association with early scanning, but also no association with admission to stroke unit within four hours of admission to hospital¹⁵. In contrast, we found that achieving early admission to a stroke unit was associated with a reduction in all-cause mortality at 30 days and six months, and results in an increased likelihood of other standards being implemented. The English study may have been subject to bias as it is a voluntary audit, and lacks the independent data collection used in the SSCA. Mortality data in our study were derived from independently collected and validated national data. We found that patients in whom stroke data were not recorded had mortality outcomes similar to those who do not achieve any of the standards. This supports evidence that voluntary reporting may result in not all patients who died being included in audit data^{16,17}.

In addition to showing that there is a reduction in all cause and stroke specific mortality with a simple care bundle, we have also shown that discharge home at 30 days is more likely if >1 standard is achieved. There was a more striking dose-response relationship at six months. This suggests an ongoing benefit on recovery from early evidence based management. Taking hospital level random effects into consideration is particularly important for this

outcome measure, as the process of care may vary, with some urban centres able to provide early supported discharge, for example, which may impact on length of stay. Mortality at 30 days is the outcome recommended by the American Stroke Association^{3,18}. Examining functional outcomes such as discharge later than 30 days may be appropriate particularly where health care models differ.

The improvement in numbers of patients achieving the standards over time may reflect the national publication of data at hospital level, and increasing awareness and training of staff at stroke unit level. Data from the US “Get with the Guidelines” Stroke program has confirmed that routine collection and feedback of data are associated with marked improvements in the quality of care¹⁹. This is supported by a Cochrane review of the impact of audit and feedback on health care outcomes at a local level²⁰, although there is less evidence of an impact of public release of performance data on changing professional or organisational behaviour²¹.

The Danish Register research has shown a negative association between process of care and medical complications after stroke; patients who had fewer medical complications (in particular pneumonia) have improved survival at 30 days and one year after stroke²². Checking for impaired swallow on admission and modifying oral intake accordingly reduces the risk of pneumonia and improves survival in some studies^{14,15}. This standard was the one least likely to be achieved in our study, and was also associated with mortality. Early antiplatelet therapy²³ and stroke unit admission²⁴ have been shown to reduce death and improve functional outcome, and these were confirmed in our study.

Strengths of this study include that this is a national dataset from one health provider with standardised guidelines and audit data collection including the SSV to correct for bias by age, stroke severity and prior status. The SSV performs robustly in published studies and has been extensively validated. There is concern about publishing tables which compare stroke

outcomes from different hospitals or health services, and on-going discussion on how best to adjust data to take case mix variation into consideration^{3,18}. In this study, adjustment of the raw data for the SSV along with year and hospital of admission enhanced the impact of achieving the full bundle on improving stroke outcomes. We removed patients with haemorrhage from analysis: thus greater than 90% of the population would be eligible for the metrics recorded, and the size of the study population reduces the likelihood of random error.

Potential weaknesses include the possibility that unmeasured variables are also likely to impact on survival and outcome. Initial patient care may be influenced by perceived futility of stroke specific intervention due to pre-existing frailty, dementia or stroke severity, and patient or relative choices regarding care pathways. We have gone some way to address this by removing from the analysis all patients who died within three days from analysis (Appendix II). We have not specifically measured dementia, but the SSV does take pre-existing independent living into account. We do not formally record functional outcome at discharge with, for example, the modified Rankin scale, but discharge to usual residence is used as a surrogate measure.

Further limitations of this study may include the possibility that patients with more severe strokes may have been imaged more rapidly, while those with milder strokes are less likely to be scanned early⁷. The SSV incorporates a measure of stroke severity, which reduces this potential bias; additionally the SSV has been validated for 6 and 12 month outcomes. In keeping with other studies^{7,14,15} we have corrected for the potential bias of clustering by hospital by correcting for this in analysis. Missing data is also a potential limitation which we addressed by removing patients with missing case mix variables from outcome analysis.

Implementation of evidence based care standards requires time and effort in health care settings. There are a limited number of studies looking at public reporting of performance

measures and subsequent improvements in quality indicators or patient outcomes after stroke¹³. The data show that both data capture and the percentage of stroke patients achieving the standards have improved over time. This may reflect increased awareness of performance driving local service improvement, along with on-going staff education and increasing proportions of patients accessing the stroke unit.

In summary, we have confirmed that achieving a simple set of quality standards was associated with reduced mortality at 30 days and six months after stroke, when known predictors of outcome are taken into account. Achieving more components of the stroke bundle at admission is associated with an increased likelihood of discharge home, and is a finding that is worthy of further exploration.

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Disclosures

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Table 1. Baseline characteristics of patients with ischemic stroke in SSCA 2005-11.

Characteristic	Patients (n=36055)
Age (years) at admission (mean/median (interquartile range))	73.3/75.4 (65.4-83.0)
Female	18495 (51.3)
Independent before stroke	28115 (78.0)
Living alone before stroke	12963 (36.0)
Can walk at admission	14140 (39.2)
Can talk at admission	26588 (73.7)
Orientated at admission	22061 (61.2)
Can lift both arms at admission	22548 (62.5)
Deprivation category 1	8266 (22.9)
Deprivation category 5	4760 (13.2)
Length of stay in hospital (mean/median (interquartile range))	29.5/13.0 (5.0-36.0)

Values are numbers (percentages) of patients unless stated otherwise.

Figure 1: Percentages of patients achieving standards over the period 2005 to 2011.

Table 2: Number (percentage) of patients and the effect of achieving each individual standard on all-cause mortality at 30 days.

Standards	Number of patients (%) achieving the standard (Total = 36055)	Adjusted* OR (95% CI) for mortality at 30 days	Adjusted* OR (95% CI) for mortality at 6 months
<i>Stroke unit on Day 0 or 1</i>	21176 (58.7)	0.82 (0.75-0.90)	0.79 (0.74-0.85)
<i>Swallow screen on Day 0</i>	27790 (77.1)	0.88 (0.77-0.99)	0.95 (0.86-1.04)
<i>Brain scan on day 0</i>	27893 (77.4)	1.07 (0.96-1.19)	0.95 (0.88-1.03)
<i>Aspirin on Day 0 or 1</i>	30446 (84.4)	0.39 (0.35-0.43)	0.54 (0.49-0.58)

*Adjusted for SSV, year of admission, and hospital level random effects.

Table 3: All-cause mortality according to number of standards achieved

Number of standards achieved (n)	All-cause mortality at 30 days n (%)	All-cause mortality at 6 months n (%)
<i>0 (269)</i>	36 (13.4)	64 (23.8)
<i>1 (2191)</i>	233 (10.6)	491(22.4)
<i>2 (6365)</i>	712 (11.2)	1413 (22.2)
<i>3 (11386)</i>	1070 (9.4)	2252 (19.8)
<i>4 (13580)</i>	1171(8.6)	2460 (18.1)
<i>Missing (2264)</i>	302 (13.3)	568 (25.1)

Table 4: Association between the number of standards achieved and all-cause mortality 30 days and six months after admission.

	All-cause mortality at 30 days	All-cause mortality at six months
Number of standards achieved	Adjusted* OR (95% CI)	Adjusted* OR (95% CI)
<i>0 vs 4</i>	2.95 (1.91-4.55)	2.26 (1.60-3.21)
<i>1 vs 4</i>	1.82 (1.51-2.19)	1.67 (1.45-1.93)
<i>2 vs 4</i>	1.62 (1.43-1.83)	1.44 (1.31-1.59)
<i>3 vs 4</i>	1.21 (1.09-1.34)	1.17 (1.08-1.27)

*Adjusted for SSV, year of admission, and hospital level random effects.

Table 5: Association between number of standards achieved and discharge to home/usual residence at 30 days and six months.

Number of standards achieved	Adjusted* OR 30 days (95% CI)	Adjusted* OR six months (95% CI)
<i>0 v 4</i>	0.88 (0.64-1.20)	0.70 (0.50-0.98)
<i>1 v 4</i>	0.85 (0.75-0.95)	0.74 (0.65-0.84)
<i>2 v 4</i>	0.94 (0.86-1.02)	0.84 (0.76-0.91)
<i>3 v 4</i>	0.98 (0.91-1.04)	0.91 (0.85-0.98)

*Adjusted for SSV, year of admission, and hospital level random effects.