

Sentinel Stroke National Audit Programme: Investigating and Evaluating Stroke Therapy (SSNAPIEST)

Protocol 1/10/15

BACKGROUND & RATIONALE

The proposed study will analyse data from the national stroke register, involving ~160,000 patient records, from ~250 stroke services in England and Wales [1] to

- identify the most clinically and cost-effective models/pathways of therapy
- factors influencing variance in equity of access to, and quality of, therapy
- the effect of that variance on outcomes

so that recommendations for commissioning and improving services can be made. This is clearly within HS&DR's remit to produce evidence on the quality, access and organisation of health services

Stroke is the most common cause of severe adult disability in the UK [3]. Treatment in a specialist stroke unit is the cornerstone of stroke care with meta-analyses showing that it reduces death and disability [4]. A fundamental element of this care is assessment and treatment by specialist stroke therapists working within a multi-disciplinary team [4].

There is growing evidence that stroke therapy is effective but needs to be provided intensively [5-9]. However most stroke patients receive little therapy and most spend most of their time inactive and alone, particularly in the UK [10-14]. Research comparing stroke rehabilitation outcomes in 4 European countries showed that UK stroke patients received less therapy and had poorer outcomes than those in Germany and Switzerland, even when confounding variables (such as stroke severity) were controlled [16]. The differences in outcome were attributed to the amount, rather than the type, of therapy and the UK's low therapy input was due to poor organisation, rather than lower staffing levels [17,18]. In an attempt to improve therapy levels and outcomes, the National Clinical Guidelines for Stroke [19] recommended that

“each active therapy required [should] be provided on at least five days a week at a level that enables the patient to meet their rehabilitation goals for as long as they are continuing to benefit from the therapy and are able to tolerate it”.

However this is rarely achieved [2].

WHY THIS RESEARCH IS NEEDED NOW

The work is needed now as the paucity of stroke therapy in the UK is a national priority [2,15,19,20]. Service managers and commissioners need objective information about quality, costs and cost-effectiveness to plan effective services, particularly under the current financial constraints.

The quarterly SSNAP reports [2] detail the amount and type of therapy provided. Several studies have described the content of stroke therapies [23-28]. There is a strong body of evidence linking the amount of therapy to outcomes [5-9]. There are however, no publications investigating influences on delivery, and variance, of therapy, nor studies of the costs and cost-effectiveness of stroke therapy services (but a little regarding specific interventions). Although the “*valuable opportunity for therapists to engage with SSNAP*” has been highlighted [2], this has not yet been attempted. Work to interrogate the SSNAP database to improve stroke care has been pioneered by Bray (co-applicant) and co-workers in their investigation of the admission and acute phases of stroke care [29-35]. We are therefore confident that the proposed work is unique and that we have the experience and expertise to complete the study.

AIMS & OBJECTIVES:

We aim to undertake an in-depth analysis of data from the SSNAP to investigate the effectiveness of stroke therapies in the UK. This will add to the useful SSNAP reports which describe stroke therapy, how it is organised and delivered [2]. Specifically we will

- Identify the different therapy pathways (such as access to other disciplines, community based services, extended working hours, for example)
- Quantify variation in therapy provision (particularly suitability for, access to, and intensity of therapy)
- Identify and quantify the organisational and patient related factors that contribute to variation in therapy provision.
- Relate the information about delivery, organisation, and variation of therapy to the quality of processes of care; patient- and service-related outcomes, and cost to identify the most clinically and cost-effective therapy pathways.
- Explore the extent of optimal resource use for each therapy pathway from the NHS perspective focusing on direct costs. It is not possible to estimate indirect costs from SSNAP data. This would be the topic of further research in the future.

Secondarily, we will also explore patient and stroke related characteristics (frequency and severity of stroke related impairments, comorbidities, demographic factors) and their association with functional recovery to identify important sub-groups of stroke survivors (people with spatial neglect, for example). We will then be able to examine the (inpatient and community based) therapy and other processes of care received and the outcomes (at discharge from hospital and 6 months post stroke) of each sub-group. This information will equip us with realistic NHS data with which to design future research trials of stratified stroke rehabilitation pathways and/or service re-organisation.

Specific questions to be asked

Describing and evaluating the organisation and delivery of stroke therapy

- Which stroke therapy models/pathways are used? How many stroke services include Early supported discharge; Community Stroke Rehab Teams; access to other disciplines; staffing levels; working hours; duration and intensity of community services? and in what combinations?
- How much variation exists in the amount of each therapy received?
- Which organisational and patient related factors influence and amount and type of therapy provided?
- After allowing for differences in the 'case-mix' of patients' demographic and clinical characteristics, does this heterogeneity exceed chance variation and can it be explained by organisational factors?
- How does the amount, type and variation of therapy provided influence outcome?
- How much does each therapy model cost?
- Which therapy models are associated with the best outcomes for each patient group?
- Which therapy models are the most clinically- and cost-effective for each patient group?
- What are the relationships between the therapy workforce and outcome (as above)?
- What are the relationships between the therapy working hours and outcomes (as above)?

Describing and investigating stroke sub-groups

- What is the frequency and severity of stroke related impairments and activity limitations?
- Which impairments are commonly co-morbid and to what extent?
- Do patients with common co-morbidities receive different amounts of therapy or achieve different clinical outcomes?
- Which other patient-related characteristics influence the outcomes of the stroke sub-groups

METHODS

Datasource: The SSNAP database [1] is the first stroke register in the world to collect information about the entire stroke pathway from hospital admission to long-term follow-up. It was established in 2013 as a national audit resource to provide data about the quality of stroke care for use to improve services. It currently involves ~250 stroke teams in England and Wales, and 95% of all stroke patients admitted to hospital (~80,000 per year). It covers the problems the stroke causes; recovery made, and treatment received from both hospital and community based services. The programme is guided by the Intercollegiate Stroke Working Party (including 2 of our applicants; Bowen and Bray) and managed by the Stroke Programme in the Clinical Effectiveness and Evaluation Unit of the Royal College of Physicians. It is centrally funded by the Healthcare Quality Improvement Partnership on behalf of NHS England. Data are updated regularly. We will use the most recent dataset for a 24 month cohort (July 2013 –July 2015; ~160,000 stroke patient records).

The data are routinely extracted from prospective local care records and submitted to the SSNAP programme by NHS staff in the participating stroke services via a secure web based tool. The webtool includes real-time data validation checks and records of individual episodes of care cannot be submitted until all data fields are completed. These audit data are linked to extracts from Hospital Episode Statistics (a nationally collected dataset of hospital activity) and the national register of death notifications. Data linkage is carried out in accordance with information governance standards and patient identifiable information is not available to the researchers. Patient consent is not obtained as all data are collected routinely as part clinical practice for the purpose of quality improvement, but patients can request to opt out of data collection.

In addition to collecting prospective patient data, SSNAP also collects cross-sectional data every two years on the organisation of all inpatient stroke services in England, Wales and Northern Ireland. This covers the characteristics of stroke services including facilities; staffing (including therapist staffing levels); organisation; use of protocols; leadership; education and training. The most recent survey was carried out in June 2014 which will be linked to the patient data and included in the analyses.

The information we will use for the analysis includes:

Organisational Factors

- Access to therapy on discharge (Early Supported Discharge and/ or Community Stroke Rehabilitation Team)
- Size of unit/ number of stroke specialist beds
- Access to other members of the Multi-disciplinary team (eg Social Work, psychology)
- Day and/or time of admission
- Waiting time for treatment by community based services
- Therapy workforce (Number of therapists/ staffing levels and skill mix)
- Working hours and days therapy is available

Processes of care

- The proportion of patients considered suitable for therapy
- The proportion of suitable patients receiving the recommended amount of therapy (45 mins/ day/ therapy for a 5 day service or 32 mins/ day/ therapy for a 7 day service)
- The amount (minutes) of therapy received
- The number of patient days in which each therapy was received
- Completion and timeliness of assessments (and reasons for lack of assessments) (continence plan; mood and cognition screen; therapy assessments)
- Presence of an early mobilisation policy
- Rehabilitation goal(s) are identified and shared with the patient
- Organisation / function of the multidisciplinary team

- Discharge planning (whether the following occurs: joint health and social care plan; treated by Early Supported Discharge team; named contact/ key worker on discharge)

Patient characteristics and outcomes

- Individual elements of the NIHSS score e.g. specific impairments on admission
- level of (dis)ability (modified Rankin Score pre-morbidly, on admission, discharge and 6 month follow up)
- functional recovery (change in modified Rankin Score between admission, discharge, and 6 month follow up)
- Stroke type
- number and type of medical co-morbidities
- patient demographics – age, gender
- frequency of complications (urinary tract infection or pneumonia)

Service related outcomes:

- completion rates for processes of care (above)
- mortality
- length of hospital stay
- length of community based treatment
- destination on discharge (including whether early supported discharge was provided)
- assistance needed for daily living after discharge from formal and informal carers

Participants: We will use SSNAP data from consecutively admitted stroke patients who are 'candidates for stroke therapy'. Those who survive and are:

- still an in-patient after 72hours
- conscious but not receiving end-of life care
- identified as needing a stroke therapy as an in-patient or after discharge from hospital.

We will include patients aged over 18 years with ischemic stroke or primary intracerebral haemorrhage.

Setting/ Context: Hospital and community based stroke services in England and Wales

Data Collection: As the data we need have already been collected, anonymised, uploaded and undergone quality control checks, we do not need to undertake any data collection or NHS approvals for the work. We will go through the established process to request that SSNAP extract a 'bespoke dataset' of anonymised data from patients meeting the criteria detailed above.

Statistical Analysis: We will analyse the data for physical, occupational and speech and language therapy separately as well as collectively (where appropriate). We will first describe average, and the variation in the therapies received (total time, frequency and duration of each therapy) and define the therapy pathways/ models available. We will model the therapy provision using mixed effect regression methods to account for patient-level factors (e.g. stroke severity, age) that will identify which factors influence therapy provision and the extent of unexplained variation. This will allow us to ascertain whether heterogeneity between centres exceeds expectation based on 'case-mix' alone. We will then extend our regression models by linking them with SSNAP's organisational data to incorporate factors such as staffing levels and working hours (whether therapy is available over the weekend) to determine the effects of each of these factors and whether they explain the variation in therapy provision between Stroke Units with similar staffing levels. This will tell us about the ways stroke therapy services are organised, which factors affect whether a patient does, or does not, receive therapy, how big that effect is, and which methods are most effective. A similar modelling approach will be used to identify and quantify associations with clinical outcome for both patient and organisational factors.

'Patient-level identifiers' allow us to track patients who move between services including those who are discharged to community based services, limiting the sensitivity of results to potential informative censoring. Reasons for missing data will be thoroughly investigated and multiple imputation undertaken if indicated. This means we will be able to cover all stages of stroke care.

For our secondary aim, we will tabulate the (frequency and severity of) stroke related physical and psychological impairments and other patient characteristics. We will use standard regression methods to identify which stroke related co-morbidities are associated with reduced therapy input by each discipline, and which are associated with longer term recovery. This will tell us whether there are sub-groups of stroke patients; which types of patients are in each group; what therapy they receive and how well they recover.

Health Economic Analysis: Using information on resource utilization by patients receiving each therapy pathway, we will ascertain the cost of each therapy pathway by attributing relevant NHS and Personal Social Services Research Unit cost data. The main resources will include hospital visits via the linked Hospital Episode Statistics data. The defined therapy pathways will be compared to each other and with the standard of care pathway (as recommended in national guidance [19]) defined as the 'base model'. Incremental cost effective ratios will be estimated for the alternative models, i.e. cost per effect. The SSNAP data do not include EQ-5D (a measure of quality of live used to calculate the effects of different treatments). Hence we are unable to estimate costs per Quality Adjusted Life Years (QALYs) or Quality Adjusted Disability Years (QADYs), but we will estimate cost effects in terms of mortality, reduced length of hospital stay, institutionalisation, and assistance with daily live (from formal and informal carers). The optimal therapy pathway, in terms of cost per effect, will be derived from the cost effectiveness modelling using standard dominance strategies.

NHS cost savings will be estimated by attributing cost of the improved outcomes to the standard cost of stroke using techniques previously developed for the UK and Europe by Gannon (co-applicant) [36]. Furthermore we will explore the impact of patient characteristics and organisational features using econometric modelling techniques, which will allow us to separate out varying effects for each therapy pathway. We will assess the impact of different resource use on efficiency of outcomes (e.g. length of stay) using data envelopment analysis or stochastic frontier modelling. This will be achieved first as technical efficiency (output measured as length of stay) and second as cost efficiency, output measured in costs.

This will tell which way of organising stroke therapy is most cost-effective

OUTPUTS & DISSEMINATION PLANS

The main output from this project is information about WHO does, or does not, receive stroke therapy and WHY. This is important information needed for evidence-based service planning and decision-making for stroke therapy services. The service improvements that emanate from the findings will benefit stroke survivors and their families, clinicians, stroke service managers, commissioners.

Greater knowledge and a clearer understanding of the influences on therapy provision, outcomes and costs will identify factors associated with both good and poor performance, which can be used to improve services and develop effective and efficient services models. In turn, this will improve outcomes for stroke survivors and their carers. As stroke therapy can reduce morbidity and the need for assistance, application of the findings could, ultimately, also reduce the demand, and costs of, long-term health and social care.

Completion of our secondary aim to define sub-groups of stroke patients will produce information to support future development of stratified stroke therapy pathways. As the treatments pathways will more accurately match patients' needs, we can expect them to be more effective, so patients make greater recovery and need less long-term support from health and social care services. This will, ultimately, enable accurately tailored efficient and effective services to be offered to individual patients and their families.

We will disseminate the findings to academic audiences through publication in high quality peer reviewed journals. Primarily the NIHR HS&DR Journal, but also other stroke and rehabilitation related journals, giving priority to open access publications. We will also present the finding at conferences such as the UK Stroke Forum, Society for Research in Rehabilitation and Health Services Research Network Symposium

To ensure the findings are made easily available to clinical audiences, for implementation in to practice, a report summarising the findings will be disseminated widely through the National Stroke Improvement Bulletin; SSNAP website; Manchester Academic Health Science Centre; Academic Health Science Networks; Strategic Clinical Networks; Commissioning Support Units; the CLARHC networks; Intercollegiate Stroke Working Party (who produce the National Clinical Stroke Guideline) to support the inclusion of our findings into recommendations for clinical practice. We will publicise them more directly to clinicians through a study day on completion of the study. Our collaborators on the advisory board (detailed below) will advise further on strategies to ensure the results are made available to service commissioners, stroke service managers and clinicians and included, as appropriate, in national guidance and policy.

We will disseminate the findings to stroke survivors and the general public through the publicity offices of the University of Manchester using press releases, relevant websites, Facebook, blogs and Twitter. We will work with the PPI panel to produce suitable material for stroke survivors (including aphasia friendly material) which will be distributed through our websites, newsletters, extensive network of stroke support groups in Greater Manchester; the Stroke Association; and our database of stroke survivors who wish to be kept informed about our stroke research.

PLAN OF INVESTIGATION & RESEARCH TIMETABLE

The project is for 18 months and involves four work packages (WP) (Gantt chart is uploaded in the flowchart section)

Set-up: before kick-off

- Once funding has been received, application for a bespoke data extraction from SSNAP will be submitted
- recruit study staff.

NB As this is an analysis of existing data there is no involvement R&D approvals, ethical approvals, clinical research network involvement or NHS treatment costs.

WP1 Staff Induction, data extraction and cleaning (4 months, Month 1-4).

- University induction, staff orientation, learn about stroke and SSNAP.
- Following the data extraction request, there is often some negotiations and revisions to be completed (hence submission before project kick-off). There is little need for further data cleaning as they have already undergone SSNAP's quality control processes.
- Research questions and study processes will be finalised between the study management group, the advisory board and the PPI panel
- Study staff become deeply immersed in the data
- Statistical and economic analysis plans finalised

Key deliverable for WP1 at end of month 3 = data extracted and ready for analysis

WP2 Data analysis for primary objectives (9 months, month 5-13).

- stroke therapy pathways identified
 - descriptive analyses undertaken
 - data linkage on organisational identifiers completed
 - random effects models fitted
 - resource use analyse of the data extracted and detailed accounts for each patient in each therapy pathway produced
 - Relative unit costs assigned to provide a costing for each pathway
 - Effectiveness of each pathway calculated and compared.
 - Efficiency analyses undertaken.
 - Preliminary results with checked with study team and secondary analyses completed
- Key deliverable for WP2 at end of month 13 = Analysis to address all primary objectives complete.*

WP3 (3 months, month 11-13) Analysis for secondary objectives

- Patient and stroke related characteristics described and cluster analyses undertaken to identify sub-groups
- Relationships between stroke impairments, patient characteristics, therapy input and outcomes analysed using standard regression methods
- Therapy provision, reasons for variance and recovery of the different sub-groups established

Key deliverable for WP3 at end of month 13 = Analysis to address all secondary project objectives complete.

WP4 Dissemination: (5 months, month 14-18):

- Interpretation of analysis finalised with study management group, advisory group and PPI panel;
- Report and paper writing
- Dissemination as detailed in the dissemination section.

Key deliverable for WP3 at end of month 18 = Main report submitted to HS&DR.

PROJECT MANAGEMENT ARRANGEMENTS

Tyson is the lead investigator and will take overall responsibility for the study. A statistician will also act as the project manager and take day-to-day responsibility for delivery. They and the health economist will be based in the Institute for Population Health at the University of Manchester with Vail and Gannon. The study team (appointees and applicants) will meet monthly to ensure smooth progress, with more frequent meetings as necessary to deal with any difficulties. This study team will also meet with the collaborative advisory group (Smith, Walsh, McGovern, Clarke) quarterly, and more frequently if necessary, to monitor progress and provide advice and expertise. Tyson and the project manager will also meet regularly with the PPI panel during the project to obtain their perspective and advice.

Financial and research business support will be provided by the University of Manchester.

There are few barriers to this project, it is very low risk. As the data has already been collected and quality checked, there is no risk of the usual causes of delay or project failure: There is no need for recruitment, concern over adherence to the treatment or assessment protocols; nor risk of delays obtaining ethical or R&D approval or the need to negotiate NHS (excess) treatment costs or clinical research network support.

The process of agreeing the bespoke dataset from SSNAP can be prolonged and involve some negotiations. However Dr Bray is very familiar with the process and we will start it as soon as we have notification of funding to avoid any delays.

An appropriately qualified and experienced project manager/ statistician and health economist have been identified in the University's Institute of Population Health, which will minimise the risks associated with staff appointments

ETHICS APPROVAL

As the patient data are anonymised, have already been collected and quality checked, we do not believe that ethical approval is necessary. However we will seek confirmation on notification of funding and obtain any approvals required. There is no need to obtain NHS R&D approvals, or the need to negotiate NHS (excess) treatment costs or clinical research network support.

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