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20 years of researching stroke through audit

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In 1988, the Kings Fund published a consensus statement identifying problems with the delivery of stroke services\(^1\). Revisiting the document now makes for uncomfortable reading. Despite the work of the last 30 years the issues remain much the same. They describe misunderstandings and rivalries between professionals, breakdown of communication between professionals, patients and their carers, insufficient appreciation of the impact of stroke on the patient’s family, ill prepared and sometimes unplanned discharge home, a serious shortage of therapy and long periods during which patients are unoccupied. There was a failure to recognise and respond to mood disturbances, delegation of care to inadequately trained medical staff and confusion caused by too many people being involved in the patients care. The only criticism that is not relevant today is that there ‘is often ill-considered admission to hospital’.

In 1995 the then Director of the Research Unit at the Royal College of Physicians, London, Dr Anthony Hopkins, set up the stroke programme which has continued since, developing national guidelines for stroke, providing peer review and support for stroke services and running national stroke audit. This paper describes how the audits have been used to improve stroke care particularly focussing on the use of national data to answer questions that could not be addressed using randomised controlled trials.

**Evolution of stroke audit**

The first national audit in England was carried out in 1998 and over the 20 years since then has progressed from a retrospective case note review conducted every two years to a continuous prospective audit of all patients admitted to hospital with ischaemic stroke or primary intracerebral haemorrhage [Table 1]. The Sentinel Stroke National Audit Programme (SSNAP)\(^2\) collects patient level information prospectively about stroke care for approximately 95% of acute stroke hospital admissions from all 142 acutely-admitting hospitals in England, Wales and Northern Ireland. Scotland has its own well established national stroke audit, the Scottish Stroke Care Audit. In SSNAP, patient level data is submitted by the clinical team treating the patient in real time or retrospectively via a secure web-tool which includes real time validation checks. Data are recorded on many aspects of care from admission until 6 months after stroke including information on processes of care and outcomes. The aim is to try to measure a "patient's eye view"
of key aspects of care quality as patients move along different phases of acute stroke care and rehabilitation. The purpose of the audit is to provide high quality information to clinicians, commissioners and the public about the services provided to enable them to identify where improvements were needed and to be able to compare themselves to services elsewhere in the country. However, with such high rates of participation the audit is in effect a national register of hospitalised stroke patients with about 85,000 new cases added each year. The ability to link the data to routine hospital episode statistics (HES) and to mortality data through the office for national statistics (ONS) provides a unique dataset that has been used for quality improvement research.

Over the past 20 years data from the audit has been used to address a wide range of research questions concerning the quality of stroke care and the relationship between the organisation of stroke services and patient outcomes. In this review we summarise some of the key publications over this time.

**Institutionalisation rate as a measure of outcome**

One of the earliest questions addressed using audit data concerned the apparent wide variation between hospitals in the proportion of patients discharged to a care home having previously been living at home Rates ranged between 10% in North London to 27% in the North West of England with some patients being newly institutionalised within just a few weeks of stroke onset with little prospect of further rehabilitation once they left hospital. This raised the question as to whether variation in the rate of institutionalisation could be used as a marker of the quality of care with lower rates being the result of better quality of acute care and rehabilitation. Analysis of the audit data however showed that the dominant factors driving care home admission were patient characteristics such as age and stroke severity. Barthel score at discharge accounted for 40% of variation, age alone explained 14% and when taken together with discharge Barthel and length of stay they accounted for 54% of variation. On admission 22% of the variation in institutionalisation rate could be
accounted for by total Glasgow coma score (15, <15), age and ability to walk unaided. There was very little evidence to show that the quality of care played a sufficient role in discharge destination for it to be a useful marker of the quality of care. Since that time overall rates of institutionalisation have fallen and in the most recent data only 6.4% of patients are newly discharged to a care home (SSNAP 2017). This suggests that although perhaps being not a reliable measure of care quality between hospitals, overall improvements in care and the introduction of new interventions has resulted in fewer patients being discharged to care home after stroke.

**Does stroke unit care in routine practice give the benefits shown in randomised controlled trials?**

Stroke unit based care is probably the single innovation in stroke care that has delivered the greatest benefit in terms of improved patient outcomes after stroke. Now almost all patients with acute stroke in the UK are treated in a stroke unit, but this was not always the case and nor was the evidence base so uncontested. The study addressed the question of whether stroke units were beneficial in real world practice outside of clinical trials. Using organisation, process of care and outcomes data from the 2001 audit at a time when only about a third of patients were being managed on a stroke unit during their hospital stay it was shown that case fatality after stroke was higher in hospitals with the least availability of stroke unit care, with the differences persisting after control for case mix. The process of care was better for patients managed on stroke units compared to other settings. The overall the risk of death for patients who received stroke unit care was estimated to be about 75% that of the risk for those having no stroke unit care (95% CI 60-90). These data were in line with the findings of the randomised controlled trials (RCTs), suggesting that the benefits of stroke units shown in these RCTS could be replicated in real world settings. These findings supported the Department of Health policy in England to ensure the development of stroke units in every hospital in England and now 85% of patients spend more than 90% of their inpatient stay on a stroke unit.

**Effect of age and time of week on the quality of stroke care**
Measuring and detecting inequalities in care is one of the important functions of clinical audits and is a question that several research studies have addressed using stroke audit data over the years. One of the first used data from the 2004 audit were to describe the factors that contribute to the quality of care delivered to stroke patients. Older patients were shown to be less likely to be treated on a stroke unit than younger patients (risk ratio comparing 85+ years with those <65 years 0.82 (95%CI 0.75-0.90). 71% of patients under 65 years were scanned within 24 hours compared to 51% aged over 85 years and older patients were also less likely than younger ones to receive secondary prevention and some aspects of rehabilitation, especially around higher functioning. Standards were consistently better for patients of all ages managed on stroke units compared to general wards. At weekends patients were less likely to be admitted directly to a stroke unit (risk ratio 0.77 95%CI 0.69-0.86) and brain imaging was performed less often for older (85+ years) patients (weekday 56%, weekend 40%).

With the high profile given to the ‘weekend effect’ over the last few years the audit data were again examined to identify whether over the last decade the situation has changed and whether the audit data was able to give a more granular picture of variability of care. Data from 2010 to 2012 information on over 45 thousand patients showed that patients admitted out of hours tended to have more severe stroke (haemorrhagic stroke, reduced consciousness, pre-stroke dependency) and that out of hours admission was significantly associated with longer delays in receiving a brain scan, being admitted to a stroke unit, and reduced odds of receiving thrombolysis. However, after adjusting for casemix, there was no consistent evidence of higher mortality for patients admitted out of hours, but patients admitted at the weekends had a higher risk of 30 day mortality (OR 1.14, 95% CI 1.06-1.21). Further data analysis in a paper from 2016 showed that the patterns of care are of course much more complex. With data from over 74 thousand patients four patterns of variation were identified. A diurnal pattern where care was worse at night compared to daytime (thrombolysis, brain scan within 12 h, brain scan within 1 h, dysphagia screening), a day of the week pattern (stroke physician assessment, nurse assessment, physiotherapy, occupational therapy, and assessment of communication and swallowing by a speech and language therapist), an off-hours pattern (door-to-needle time for thrombolysis), and a flow pattern whereby quality changed sequentially across days (stroke-unit admission within 4 h). There was no difference in 30 day survival between weekends and weekdays but
patients admitted overnight on weekdays had lower odds of survival (0·90, 0·82–0·99). No one working in a hospital will be surprised by these findings. If social services are unable to start personal care services at weekends, patients will not be discharged and the stroke unit will be unable to take new admissions. Hospitals are more sparsely staffed at night so it is not surprising that processes of care are slower. Many of the hospital services such as radiology are programmed only to undertake ‘emergency work at night so access to brain imaging is more difficult. These findings show that despite improvements in overall care over the past decade, the quality of care that patients receive is still at least partly dependent on the time of day or day of the week they have their stroke. If inequalities in care are to be overcome, and they must be, health and social services need to truly develop 7 day services that do not recognised the concept of a ‘weekend’.

Do patient reported measures match those obtained from the professionals recording of processes of care?

Although most people would agree that improving patients' quality of life and their own sense of health should be one of the primary aims of healthcare, in practice measuring patient reported experience of care and outcomes after stroke is difficult. Collecting this type of data outside of a research study from tens of thousands patients every year is very challenging, and can only be justified if the information is genuinely useful for improving the quality of care that patients receive. A study published in 2007 individually linked patient reported experience and outcome data to the national audit data for 671 patients cared for in 51 English hospitals. Patient experience scores were positively correlated with clinicians' assessment of the organisational quality of stroke care, but were largely unrelated to clinical process standards. Discrepancies were found particularly relating to individual questions regarding communication about the diagnosis. Whether this was because clinicians were overestimating the amount of information provided to patients or whether it was because the information given was not remembered by the patients cannot be answered, but if the patient does not recall being given information then there has been a failure to communicate adequately. This research showed how vital it is to get both professionals and patient views on the quality of care. They measure different but complementary aspects of management. Attempts to obtain funding to undertake a pilot study to try and collect patient reported outcome and experience measures by patients being given the opportunity
to answer a web based questionnaire linked to their SSNAP record has so far been unsuccessful. It has been suggested that stroke patients would not have the ability or the opportunity to undertake such data entry however, with the generation of computer literate people now having strokes in significant numbers and with family, friends and charities potentially able to support such a system, it must be something worth testing. SSNAP has been attempting to record outcome measures six months after stroke with singular lack of success. If commissioners and clinicians are unable to achieve this critical measure of quality of care then patient reported measures would be a valuable alternative.

**How do the processes of care after stroke affect mortality?**

The audits have always predominantly measured process of care (in other word, the things that happen to patients such as tests, clinical assessments and treatments) rather than outcomes. The processes of care measured in the audits were as far as possible based upon research that shows they are linked to better outcomes (such as admission to a stroke unit) but there are some measures that cannot easily be subjected to randomized controlled trials (RCTs). For example, how important is adequate hydration after stroke? No trial could ethically dehydrate patients after stroke and likewise it would be unethical to randomise patients into those who have the safety of their swallow assessed and those that are not offered screening. Data from 2010 to 2011 on 36,197 patients with acute ischaemic stroke showed that well organised stroke services were more likely to deliver high quality care. Review by a stroke consultant within 24 hours of admission (adjusted odds ratio 0.86, 95% confidence interval 0.78 to 0.96), nutrition screening and formal swallow assessment within 72 hours (0.83, 0.72 to 0.96), and antiplatelet therapy and adequate fluid and nutrition for first the 72 hours (0.55, 0.49 to 0.61) were all associated with reduced 30 day mortality.

These findings are consistent with the evidence from the RCTs of stroke unit care and help to explain what it is about stroke units that mean that they achieve better outcomes than keeping patients with stroke on general medical wards. The evidence suggests that it is “getting the basics of care” right, such as swallowing assessments, nutrition and attention to hydration, that is key to reducing the risk of dying in the first few weeks after stroke.

**Is thrombolysis safe to use in patients over the age of 80?**

Intravenous thrombolysis is still only licensed for patients aged 18-80 despite an increasing tendency for clinicians to ignore many of the licensed indications and treat older patients.
By 2012 trials had included virtually no patients over the age of 80. Using data from 2010-11, 37,151 adults were admitted with acute ischaemic stroke of whom 3,374 (9.1%) were thrombolysed. Patients aged over 80 accounted for 21% of the thrombolysis recipients and 4.8% of patients in this age group received rt-PA. Similar rates of post-thrombolysis complications (in particular intracerebral haemorrhage) were observed between patients aged over 80 years and younger patients. Mortality was higher among older patients whether they were treated with rt-PA or not and the treatment appeared to be beneficial regardless of age. Similar findings were also reported when data were examined specifically to look at thrombolysis on 122 people over the age of 90. These observational findings turned out to be consistent with the IST-3 trial, which randomised 1617 patients aged ≥80 years and demonstrated that rt-PA was similarly as effective as earlier trials had demonstrated in younger patient cohorts.

**Do bigger stroke units work better than smaller units?**

A paper published in 2013 looked at the association between the use of thrombolysis with rt-PA and the size of the stroke service as measured by the number of patients thrombolysed per annum. Patients admitted to hospitals with an annual thrombolysis volume of more than 50 cases had median arrival to treatment times that were 28 and 22 minutes shorter than patients admitted to hospitals with volumes of 0 to 24 and 25 to 49, respectively. In multivariable analysis, patients admitted to hospitals with a volume of ≥50 cases per annum had 4.33 (2.21-8.50; P<0.0001) the odds of receiving tPA within 60 minutes of arrival and the chance of receiving thrombolysis was also greater. This have been very important data informing the delivery of stroke care in England where many hospitals have been running small services often with fewer than 400 admissions a year. Being able to show clear data showing that bigger can be better has enable difficult decisions to be made about the need to focus care in a smaller number of larger units.

Use of national audit data was integral to the analysis of the effects of the reconfiguration of stroke services in London which also showed better process of care and lower mortality after reducing the number of acutely admitting hospitals from 32 to 8.

**Do staffing levels matter?**

Another area where it would be impossible to undertake a RCT is to determine whether stroke unit staffing levels have an impact on the quality of care and outcome.
outcomes from the national audit data it was shown that there was a relationship between weekend nurse/bed ratios and mortality risk, with the highest risk of death observed in stroke services with the lowest nurse/bed ratios. In multivariable analysis, patients admitted on a weekend to a SU with 1.5 nurses/ten beds had an estimated adjusted 30-d mortality risk of 15.2% (aHR 1.18, 95% CI 1.07-1.29) compared to 11.2% for patients admitted to a unit with 3.0 nurses/ten beds (aHR 0.85, 95% CI 0.77-0.93), equivalent to one excess death per 25 admissions. There was no association found between mortality risk for patients admitted to a stroke service with stroke specialist physician rounds fewer than 7 days per week (adjusted HR 1.04, 95% CI 0.91-1.18) compared to patients admitted to a service with rounds 7 days per week. These findings are consistent with a large body of literature from across healthcare that having higher nurse staffing ratios results in better patient outcomes. Although perhaps self-evident that having each nurse look after a larger number of patients might result in poorer quality care, having good quality evidence has been helpful in informing guidelines and persuading policy makers of the importance of maintaining staffing ratios in a time when healthcare budgets are under ever-increasing pressure.

**Does assessing the safety of swallowing really make a difference?**

It has been assumed for years that identifying dysphagia early and then having specialist speech and language therapy assessment is a good thing. But there was little evidence to show that it did affect outcomes. The national audit data enabled evidence based medicine to catch up with common sense medicine and has also shown that the decision to set the time limit to swallow screening from admission to 4 hours as compared to 24 hours as recommended in American guidelines is correct. Of 63 650 patients admitted with acute stroke, those with the longest delays in dysphagia screening (4th quartile adjusted OR 1.14, 1.03 to 1.24) and speech and language therapist (SALT) dysphagia assessment (4th quartile adjusted OR 2.01, 1.76 to 2.30) had a higher risk of Stroke Associated Pneumonia (SAP). The risk of SAP increased in a dose-response manner with delays in SALT dysphagia assessment, with an absolute increase of pneumonia incidence of 1% per day of delay17.

**Making decisions about end of life care in patients with haemorrhage and ischaemia**

There was a clinical concern that patients with primary intracerebral haemorrhage (ICH) have a worse prognosis in part because clinicians make premature (and overly pessimistic)
decisions about prognosis. Data from the national audit were analysed for a total of 65,818 patients. After ICH (n = 7020/65,818, 10.7%), 10.5% were palliated on the day of admission and 19.3% by 72 h (vs. 0.7% and 3.3% for ischemic stroke). This was independent of level of consciousness (a good marker of stroke severity), age, and premorbid health. When compared to ischemic stroke therefore, patients with ICH were much more likely to commence palliative care during the first 72 h of their care. This raises questions about whether these decisions are always made with a good understanding of prognosis\textsuperscript{18}. In other words these data suggest that there may be patients who may be dying because of inappropriate decision making by clinicians who do not fully understand the natural history of intracerebral haemorrhage.

**Does socioeconomic status influence the risk of stroke, outcome after stroke and the quality of care?**

It is well recognised that lower socioeconomic status increase the risk of illness and premature death and this has also been documented specifically for stroke. However, no study of this scale and none has looked both at incidence and the quality of care\textsuperscript{19}. Of the 43·8 million adults in England, between 2013 and 2016, 145,324 people were admitted to hospital with their first-ever stroke: Patients from the lowest socioeconomic groups had first stroke a median of 7 years earlier than those from the highest (p<0·0001), and had a higher prevalence of pre-stroke disability and diabetes. They were also less likely to receive five of 12 recommended care processes but were more likely to receive early supported discharge (adjusted odds ratio 1·14, 95% CI 1·07-1·22). Low socioeconomic status was associated with a 26% higher adjusted risk of 1-year mortality (adjusted hazard ratio 1·26, 95% CI 1·20-1·33, for highest vs lowest deprivation decile), but this gradient was largely attenuated after adjustment for the presence of pre-stroke diabetes, hypertension, and atrial fibrillation (1·11, 1·05-1·17). The SSNAP data therefore has shown major inequalities in stroke risk according to financial status and major inequalities in the delivery of care depending on where a patient lives and when during the week they have their stroke. Only with data such as these can remedies be put into place to rectify the issues.

**How much does stroke really cost in England, Wales and Northern Ireland?**

Using audit data\textsuperscript{20} it has been possible to calculate in detail the exact cost of stroke care and to be able to determine differences in cost based on stroke type and patient characteristics.
The total cost of health and social care for patients with acute stroke each year in England, Wales and Northern Ireland was £3.60 billion in the first five years after admission (mean per patient cost: £46,039). There was fivefold variation in the magnitude of costs between patients, ranging from £19,101 to £107,336. Costs increased with older age, increasing stroke severity and intracerebral hemorrhage stroke. It showed that as expected patients with stroke secondary to atrial fibrillation cost significantly more providing more evidence to use to persuade politicians and health care planners to invest in more effective detection and management of patients with atrial fibrillation. Increasing the proportion of eligible patients receiving thrombolysis or early supported discharge was estimated to save health and social care costs by five years after stroke. The latter information is important and useful in helping to make the case that improvements in care quality can also help to reduce the financial burden of stroke on health and social care providers.

The Potential Strengths and Limitations of Using Audit Data for Research in Rehabilitation

The principal purpose of collecting national audit data is to provide information back to clinical services to help them understand the quality of care that they provide, how they compare to others and what they might do to improve. As the range of these studies show, this type of data is also extremely valuable in supporting research that helps to provide some of the evidence base to guide quality improvement and decision making on how best to configure healthcare services. Registry based studies have several strengths, including large sample size, detailed information on clinical process measures and the ability to carry out research at much lower cost than studies where new data has to be collected. The use of real world data, drawn from (relatively) unselected cohorts and treated by many hospitals and teams, often means that that registry based studies have high external validity. The trade off comes in that the amount, and likely quality, of the data collected on each participant is less than would be achieved in a stand-alone epidemiological study or trial. Since the interventions are "real" and not randomised, estimated treatment effects are at risk of unmeasured confounding and selection bias. Some data is intrinsically hard to collect at scale, and this unfortunately includes many of the outcomes that are most important to patients, such as quality of life, disability or the psychological effects of stroke. This is one of the reasons why very few research studies using SSNAP data have addressed questions specifically relevant to clinical rehabilitation. Measuring rehabilitation practice is
complicated and the outcomes are not easily captured systematically and consistently at scale. Compared to other large scale stroke audits and registries, SSNAP is almost unique in attempting to collect some data about the amount and type of therapy provided to patients. Nonetheless, the trade-offs required to collect this data mean that it is less detailed than would be ideal for addressing rehabilitation focused questions. Despite these limitations, studies are currently underway to explore this aspect of SSNAP data (e.g. the NIHR funded SNAPPIEST study) and attempt to make use of this unique data resource to address some of the many unanswered research questions in post stroke rehabilitation.

Conclusions
There is no doubt that stroke care has improve over the last 30 years since the Kings Fund report, but equally rehabilitation services have failed to match the progress made in prevention and acute care. In part this has been due to the lack of a strong enough clinical and health economic evidence base to persuade commissioners and providers that it is worth investing their limited resources. Randomised controlled trials in rehabilitation are important but difficult to perform. Quality registers such as SSNAP provide an additional way of identifying what works in rehabilitation and where treatment would be better directed to alternative therapies. The SSNAP database now contains detailed information on over a third of a million stroke patients with full data covering care from the acute admission to hospital discharge. Most early supported discharge teams enter data on their patients but later stages in the patients’ pathway have much lower rates of data submission. Only about a third of patients have their 6 month status recorded. This severely limits the ability to assess the longer term effects of acute care and rehabilitation. It is an invaluable resource that few other countries can match. It would be even more valuable if the data was complete for the community interventions and longer term outcomes.
### Design of clinical audit

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>Sentinel</strong> 1998 - 2010</td>
<td>Cross sectional audits every 2 years. Data collected on a sample of patients admitted to hospital with acute stroke</td>
</tr>
<tr>
<td><strong>SINAP</strong> 2010 - 2013</td>
<td>Continuous prospective audit of all patients admitted to hospital with acute stroke, focussing on quality of care in the first 72 hours after admission. Approximately 2/3 of eligible hospitals participated</td>
</tr>
<tr>
<td><strong>SSNAP</strong> 2013-Present</td>
<td>Continuous prospective audit of all patients admitted to hospital with acute stroke, focussing on quality of care from admission up to six months after stroke. Almost complete participation from hospitals in England, Wales and Northern Ireland and many community stroke teams</td>
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Table 1. Evolution of clinical audit of stroke care in England, Wales and Northern Ireland
Key audit research findings

- Larger stroke units perform better than smaller units
- Higher nurse staffing levels save lives on stroke units
- There are inequalities in stroke risk and care depending on financial status, where the patient lives and what time of day or day of the week the patient has their stroke
- Early assessment and intervention by a speech and language therapist of the safety of the swallowing mechanism reduces the risk of stroke associated pneumonia
- Thrombolysis is safe and effective in older patients
- Stroke units save lives and reduce disability in real life and not just in randomised controlled trials
- Specific processes of care such as early fluids result in a lower risk of death
- If one wants to really understand the quality of the stroke services it is important to measure not just the processes of care but the patients views of their outcomes and experience of care

Table 2. Some of the key research findings from Clinical Audit in England, Wales and Northern Ireland
12. The benefits and harms of intravenous thrombolysis with recombinant tissue plasminogen activator within 6 h of acute ischaemic stroke (the third international stroke trial [IST-3]): a randomised controlled trial. Lancet 2012;379:2352 - 2363


