Cadilhac, Dominique A. and Fisher, Rebecca J. and Bernhardt, Julie (2017) How to do Health Services Research in stroke: a focus on performance measurement and quality improvement. International Journal of Stroke . ISSN 1747-4930 (In Press)

How to do Health Services Research in stroke: a focus on performance measurement and quality improvement

Journal:	*International Journal of Stroke*
Manuscript ID	IJS-07-17-5838.R1
Manuscript Type:	Leading Opinion (invited)
Date Submitted by the Author:	n/a
Complete List of Authors:	Cadilhac, Dominique; Monash University, Medicine; The Florey Institute of Neuroscience and Mental Health, Stroke: Public health Fisher, Rebecca; University of Nottingham, Rehabilitation and Ageing Bernhardt, Julie; Florey Neurosceince Institutes, AVERT
Keywords:	Stroke, Health Services Research, Quality Improvement, Methods, Protocols, Implementation Science

How to do Health Services Research in stroke: a focus on performance measurement and quality improvement

Dominique A Cadilhac[1,2], Rebecca Fisher[3], Julie Bernhardt[2]

1. Stroke and Ageing Research Centre, School of Clinical Sciences at Monash Health, Monash University, Clayton, Victoria Australia
2. Florey Institute of Neuroscience and Mental Health, Heidelberg, Victoria Australia
3. Division of Rehabilitation and Ageing, School of Medicine, University of Nottingham, United Kingdom

Author for correspondence: Dominique A Cadilhac

Phone: +61 3 8572 2657

Email: dominique.cadilhac@monash.edu

Key Words: Stroke, Health Services Research, Quality Improvement, Methods

Table 1: Most common study types used in Health Services Research

Table 2: Considerations for establishing a stroke registry or audit program for measuring the quality of care

WORD COUNT: 5565 (title page 123, abstract 100)

ABSTRACT

The objective of this 'How to' research series article is to provide guidance on getting started in Health Services Research. The purpose of health services research is to contribute knowledge that can be used to help improve health systems and clinical services through influencing policy and practice. The methods used are broad, have varying levels of rigour and may require different specialist skills. This paper sets out practical steps for undertaking health services research. Importantly, use of the highlighted techniques can identify solutions to address inadequate knowledge translation or promote greater access to evidence-based stroke care to optimise patient outcomes.

Introduction

Health services research is rapidly gaining momentum as an interdisciplinary field that examines the organisation, delivery and financing of health care with the aim to improve patient outcomes.(1) Health services research contributes knowledge that can be used to help improve health systems and clinical services through influencing policy and practice. Therefore, the methods used are very broad, have varying levels of rigour and may require specialist skills.

Clinical guideline recommendations help us determine the most essential, evidence-based aspects of care that should be delivered. Quality of care is often gauged by monitoring routine care against these evidence-based standards. However, many therapeutic interventions, effective in clinical trials and subsequently recommended in clinical guidelines, are often inconsistently used in practice (2) and new evidence is slow to be implemented (3) to the likely detriment of patients. Reasons for this poor translation include misalignment between the focus of the research; feasibility of application in different contexts, and the knowledge needs of policy makers and practitioners.(4)

An important role of health services researchers is to design and evaluate quality improvement initiatives to help bridge the research evidence to practice divide. Within the field of stroke, poorer quality in hospital care has been shown to be associated with potentially avoidable deaths and disability.(5-8) Countries using national audit data or registries to support stroke service re-configuration, have demonstrated positive impact.(9-11) When inequality in service provision (also known as unwarranted variation in practice) is identified, evidence-based methods for addressing service gaps are needed.

The term ‘complex healthcare intervention’ applies to most stroke care; where both the intervention(s) and the context (or system) in which care takes place has many component parts, increasing the unpredictability of effects.(12) Therefore, understanding the cause and effect pathway is not straightforward and knowledge of the health-care system is required. Health services researchers use applicable theories, as well as a range of methods to help clarify the associations between complex interventions and health outcomes.(13) Understanding how complex interventions operate outside of clinical trial conditions and within real world contexts is vital, and is the focus of ‘knowledge translation’ or ‘implementation’ research which also covers the issue of sustainability.

This article describes common approaches that embrace different aspects of health services research, offering practical guidance for new researchers in the stroke field. Since understanding how therapeutic interventions operate in the real world is as important as designing improvement initiatives aimed at facilitating change, there is a particular focus on performance monitoring and quality improvement. Specialised areas of health services research, such as economic evaluation are not covered in detail. Where relevant, the authors have drawn on their own research and that of others to provide pertinent examples of the various methods and their application which are relevant to a range of settings and countries.

How to get started

The most important first step is being clear about your research or evaluation objective and working through how your results will be used. For example, if you want to influence policy it is important that your research question is of relevance to policy makers. Involving the people who will apply your research findings early in the process of study design is important.(4) This approach is often referred to as ‘co-production’ or ‘co-design’ whereby a

dynamic, experimental, and reflective process is sustained by different forms of engagement throughout a project with end users.(14) Importantly, users provide mutually valuable contributions and are regarded as equal and active agents and not merely passive subjects or recipients of services.(15) For example, holding a workshop or regular meetings that includes all relevant stakeholders as part of designing and conducting your research is essential. For a contemporary example of how co-production has been used in stroke see Hearton et al.(15)

Additional consideration is needed when end-users are patients or lay members of the public as part of supporting co-production. These considerations include the use of plain language so that communication is inclusive, reimbursement for travel/parking, suitable scheduling of meetings, facilitation that promotes equal opportunities to participate and the ability to contact project staff or receive paperwork via alternate methods (i.e. not just electronically).(16)

Ethical considerations: Depending on your local requirements for maintaining privacy or the type of data you are collecting, you may or may not require ethics or other governance approvals. Generally, if you are going to publish your results in a peer-reviewed journal an ethics approval or exemption from a Human Research Ethics Committee is required.

Designing your study

All good research, including health services research, needs a clear research question (see 'How to do high quality clinical research'(17)). In general, a well written research question should specify the population being studied (i.e. age groups, conditions, sex), the setting (i.e. hospital, community), the intervention of interest, the comparator (or control situation), the outcome of interest, as well as the design (prospective, retrospective, randomised).

Depending on the type of research e.g. qualitative which is exploratory in nature rather than deterministic or quantitative, the research questions may include descriptive terms such as 'describe', 'explore' and 'identify'.

Study types

Often in health services research, the 'intervention' of interest may be a therapeutic complex intervention (i.e. has more than one theoretically predicted mechanism of action)(18), an exploration of a service operating in a real world setting, or a quality improvement initiative designed to improve the provision or organisation of care. Therefore, different study designs are used including observational (or natural experiments), quasi-experimental (cross-sectional, time series, controlled before and after), qualitative approaches and mixed-methods in addition to randomised controlled trials (including cluster and step-wedge designs). There is also a new frontier being explored whereby randomised trials are embedded within clinical registries as an efficient and low cost option for large-scale studies of comparative effectiveness.(19) For an example in stroke see https://clinicaltrials.gov/ct2/show/NCT02961348.

The type of design adopted depends on your question and also pragmatic considerations including funding and timeframes. Table 1 describes some common study types that have been used to conduct health service research in the field of stroke. Here we provide some further information to assist in your choice of study design and practical considerations for data collection.

Intervention effects: In health services research it is often the case that the researcher is investigating the possible effect of an intervention on participants, when assignment of

participants is outside the control of the investigator (e.g. a policy initiative). In many cases, delivery of the intervention itself is also not under the control of the researcher (e.g. stroke unit care). These scenarios have been referred to as natural experiments and come under the domain of observational research.(20) Randomised and quasi-experimental designs in which intervention assignment is controlled in some way, are also valid for quality improvement projects (e.g. intervention designed to change behaviour). In an attempt to mitigate risks of bias, quasi-experimental study designs include a comparator of some kind, which tends to act as a 'control' group (e.g. participants either receiving no or a different kind of service or intervention).(21)

Health services research, focused on performance monitoring or quality improvement, usually involves evaluation of some kind; of the health service itself or of quality improvement approaches designed to facilitate greater access to evidence based care. Knowing whether an intervention has resulted in the hypothesised effects is assessed using impact or summative evaluation. Impact evaluation is the systematic study of the change that can be attributed to a particular intervention, program or policy and relies on having standardised data at various time points. In contrast summative evaluation is used to assess the longer term outcomes of a program or intervention including sustainability of effects. It is worth remembering that studies of this type usually include a reliable process for identifying barriers to the intervention achieving its effects (22). A behaviour change improvement intervention designed to facilitate delivery of evidence based care would be based on existing evidence for overcoming such barriers (23, 24) (see Long-term implementation section below). The study designs outlined above to assess intervention effects are relevant to conducting impact and summative evaluations. For a web-link to a useful glossary of evaluation terms see Appendix 1 (online supplement).

Researchers also need to understand *how* interventions (as proven effective in a clinical trial) might be implemented and operate in real world settings. *Process evaluation* is one methodological approach used and there is comprehensive guidance available.(22) It is particularly useful alongside randomised controlled trials, to enable description of how the intervention was delivered during the trial, including any training and resources required; description of any adaptations being made (fidelity), who got the intervention (reach) and how much of it (dose).(13) This allows investigation of mechanisms of impact including participant perspectives and unexpected pathways or consequences. It also enables the researcher to begin to identify contextual factors that may influence the implementation of the intervention or the outcomes achieved.(13, 22) For an example, please refer to the process evaluation for the Quality in Acute Stroke Care (QASC) trial.(23)

Process evaluation may also be used alongside other study designs including controlled before and after studies where it is not feasible to conduct a randomised trial of a complex intervention used to change clinical practice for a proven intervention e.g. use of telemedicine to increase access to acute stroke thrombolysis.(24) *Where process evaluation has been used in addition to the primary study design this is an example of mixed methods research*. Mixed-methods offers powerful tools for investigating complex processes and systems in health care whereby the researcher is able to use different and complementary forms of data to verify the extent to which the qualitative and quantitative findings cohere.(25) Overall, the use of multiple data sources and triangulation of results (*see Data analysis section*) provides a broader means of ensuring comprehensiveness and encourages a more reflective analysis of a program or innovation.(26)

Long-term implementation: Performance monitoring and quality improvement also require an understanding of how evidence-based treatments and interventions can or are being adopted, sustained, or improved in real-world environments. To ensure standardised monitoring for these activities, data are usually captured in a clinical quality registry or audit program. Table 2 provides an overview of considerations for establishing a stroke registry or audit program for monitoring the quality of care.

Theoretical models developed in implementation science can help in the choice of study design and with decisions about what data to collect (see Appendix 1 for examples).(27, 28) In general these models emphasise the importance of identifying 'core components' or active ingredients of the therapeutic intervention of interest; components hypothesised to be core to performance in practice. Examples of this in stroke include studies investigating the implementation of Early Supported Discharge or the impact of stroke unit care.(29, 30) These models can also help further navigation of what is meant by context, by offering categories in which contextual factors may sit (which can inform data collection strategies). An understanding of context involves an assessment of people and organisations, as well as the interaction of the desired behaviour (e.g. implementation of an evidence-based intervention) within the context in which it is implemented. Therefore, the researcher needs to consider social architecture, networks and communications, culture and climate (i.e. readiness to change practice).(31) It also means that issues relating to knowledge, beliefs and behaviour change may need to be considered.(27, 28) For an example of a survey tool to assess context see the work by Estabrooks and colleagues.(32)

Theoretical models also offer guidance on how to design active approaches to facilitate quality improvements. Termed 'facilitation', these include strategies such as audit and

feedback, consensus building and reminders or more comprehensive quality improvement systems such as the plan-do-study-act cycle.(28) For examples see the Stroke 123 study protocol and pilot study of an organisation intervention to improve discharge care by Cadilhac and colleagues.(33, 34)

Economic evaluation: used when you want to determine if your intervention has been worthwhile based on changes in resources used for the patient outcomes achieved. In these types of studies the costs and outcomes of two or more alternate pathways of care are compared. Different analyses including simulation modelling may be performed based on the research question, the perspective of the study (e.g. government or patient), the type of data available, and the outcomes of interest. For further reading see Drummond and colleagues.(35, 36)

Data collection

Quantitative methods: data collection can be simple (paper-based) or sophisticated (electronic data capture) and is usually dependent on the availability of resources. Wherever possible look for a data collection tool that is able to be readily adapted for a research project that permits direct data entry into a database that can have the data exported in a format ready for analysis. There are a variety of free or low cost online tools or existing tools that can permit the set-up of a survey or the collection of data from or about patients. Examples include Research Electronic Data Capture (REDCap),(37) the Australian Stroke Data Tool (http://australianstrokecoalition.com.au/ausdat/), Registry of Stroke Care Quality (RES-Q) European Stroke Organisation see: https://www.qualityregistry.eu/index.php/en/).

In determining and defining your variables it is important to consider those already in existence. This permits comparability, reliability and reproducibility where the same type of data is to be collected in answering a research question. The UK has the well-established Sentinel Stroke National Audit Programme (SSNAP) that has been used in a number of well-designed studies (https://www.strokeaudit.org/Research/Published-papers.aspx). An example of a comprehensive stroke data dictionary is the National Stroke Data Dictionary developed in Australia for the Australian Stroke Data Tool (see http://australianstrokecoalition.com.au/site/media/AuSDaT-National-Stroke-Data-Dictionary-May-20171.pdf). For other data dictionaries see national registry websites e.g. for the Ontario Stroke Registry (Canada) see https://www.ices.on.ca/Research/Research-programs/Cardiovascular/Ontario-Stroke-Registry.

Some research questions may be answered through accessing existing data. This can save a lot of time, effort and resources by avoiding duplication. Administrative or claims data (i.e. routinely collected coded data reported to government) can be accessed or augmented through data linkage where it is possible to merge patient level records using patient identifiers (see below). Increasingly researchers are also archiving their data in data repositories for use by other researchers. Wherever possible, check whether data on your topic exists that might be suitable for your purpose. An example is the Virtual International Stroke Trials Archive (VISTA) which is a collaborative venture that collates data from completed clinical trials and provides access to anonymised data for novel exploratory analyses to inform clinical trial design (see http://www.vista.gla.ac.uk/). Many national clinical quality registries or audits may also have data accessible for secondary use.

Potential value of data linkage: Using data that already exists and supplementing it using data linkage techniques can minimise the costs of research, but still requires governance and ethical considerations to be addressed to overcome concerns about consent, the potential for re-identification of data, duality of data custodian roles and data ownership.(38) Benefits include not having to ask hospital clinicians to collect additional data or avoiding the need to interview patients at multiple time points. However, specialist analytic skills may be needed depending on the complexity of the merged data.

Qualitative data collection typically involves tape recording of interviews with key stakeholders. Structuring an interview allows researchers to frame discussions around topics of interest, thereby facilitating future data analysis but also imposing some preconceived theories or ideas on the data being collected. Unstructured interviews offer the opportunity for a more in depth investigation and are driven much more by the participant's response (but can be difficult to manage). For more information on qualitative research methods see Silverman (39) or Patton (40). It is often the case that mixed-methods health service research studies involving qualitative data collection also include 'observation', which can take the form of ethnography or behavioural mapping which require specific techniques (41, 42) (see also Online supplement).

Data analysis

Quantitative analyses: Usually descriptive statistics are able to be undertaken by a novice researcher. However, it is always ideal to partner with a statistician. For further information see the following sections of the 'How to research guide' by Sandercock and Whiteley: "The importance of training in basic epidemiology and statistics" and "Statistics – working with

statisticians and statistics packages".(17) Before analysing any form of data, processes to verify and check for data quality should be undertaken.

It is important to note that much of the quantitative research discussed so far is observational and lacks randomisation. This means that attributing causality can be difficult as there may be a risk of bias.(43) In the absence of randomisation, quantitative studies involving statistical analysis often require case-mix adjustment for certain variables and should take into account correlations that occur between patients that are managed within the same hospital (i.e. cluster effect). In addition, there may be important organisational or other features of the setting such as urban/rural location that should be accounted for in multivariable models. Therefore, there is the need for deductive an inductive approaches to undertaking analysis of quantitative data including decisions on which variables make sense to include in statistical models. Further, potential 'confounding' variables may also be important contextual factors influencing how the intervention operates in real-world settings. Therefore, health service researchers must be skilled in the use of a mixture of different study designs and capturing information related to the whole system.

Qualitative analyses: Similarly, analysis of *qualitative data* requires an acknowledgement of the differences between the deductive (top-down, theory driven) and inductive (bottom-up, explanatory) approaches.(39, 44) Qualitative research, like quantitative research, is also subject to bias. Therefore, it is important to be aware of strategies for ensuring trustworthiness.(45) These include approaches to maximise credibility (measuring what was intended), transferability (generalisability), dependability (detailed reporting) and confirmability (objectivity).

A common method of qualitative data analysis used in health services research is thematic analysis, involving identifying patterns or themes in the data. (44) This requires transcription and coding of the interview data and then grouping into themes. It is worth noting that although qualitative research is useful for descriptive purposes, it can also be used to relate findings to existing theories (about improvement or implementation).(46) Although overarching theories can seem abstract, they allow concepts to be formed across a range of different fields and study types, enhancing transferability of findings. For example, the application of normalisation process theory in process evaluations has been helpful in understanding how practices relating to delivery of an intervention can become routinely embedded in a social environment, therefore enhancing implementation.(47)

Mixed methods analyses: Triangulation is a process for combining at least two or more theoretical perspectives, methodological approaches, data sources, investigators, or data analysis methods whereby the intent is to decrease, negate, or counterbalance the deficiency of a single strategy, thereby increasing the ability to interpret the findings.(48) In stroke there are various examples where mixed methods have been used, in particular as part of studies with process evaluation data and patient-level data (for examples see (26, 49)).

Specifically three detailed examples are provided in the online supplement covering patient-level data collection (*Example 1: Clinical quality registries and audit*) or research techniques (*Example 2: Behavioural mapping and process mapping*; and *Example 3: Realist methodology*) that may be used to better understand clinician or patient behaviour in a health system.

Summary and further reading

Researchers need a better understanding on how therapeutic interventions as tested in clinical trials operate in practice. In addition, systematic methods for monitoring care and evaluating the impact of organisational interventions used to change clinician behaviour and patient outcomes are needed. This 'How to' article, introduced the broad discipline of Health Services Research, the importance of underpinning the research with existing theories was emphasised, as well as the importance of drawing on quantitative and qualitative techniques in providing a comprehensive analysis of complex interventions and health care. Within the area of stroke there are many examples of where novel approaches to redesign or improve the health care system to ensure better access to evidence-based care are being applied (e.g. telemedicine and more recently the advent of mobile stroke units).(50-52) Using the research approaches described here will ensure that comparative effectiveness of the intervention of interest can be reliably determined and that critical success factors and processes can be adequately described to support replication elsewhere. In this way, performance monitoring and quality improvement will lead to delivery of the best evidence based care for people experiencing stroke.

For further reading and to access useful websites or tools to help you design or undertake health services research studies see the Appendix (online supplement).

Acknowledgements:

The authors of this paper each report holding research fellowships: National Health and Medical Research Council: Dominique Cadilhac (1063761 co-funded Heart Foundation) and Julie Bernhardt (1058635); and Rebecca Fisher: TSA LECT 2016/01 Stroke Association HRH the Princess Margaret Senior Lecturer Award.

References

1. Lohr KN, Steinwachs DM. Health services research: an evolving definition of the field. Health Serv Res 2002;37(1):7-9.
2. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet 2003;362(9391):1225-30.
3. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. Journal of the Royal Society of Medicine 2011;104(12):510-20.
4. Wolfenden L, Yoong SL, Williams C, et al. Embedding researchers in health service organizations improves research translation and health service performance: The Australian Hunter New England Population Health example. J Clin Epidemiol 2017.
5. Cadilhac DA, Andrew NE, Lannin NA, et al. Quality of Acute Care and Long-Term Quality of Life and Survival: The Australian Stroke Clinical Registry. Stroke 2017.
6. Middleton S, McElduff P, Ward J, et al. Implementation of evidence-based treatment protocols to manage fever, hyperglycaemia, and swallowing dysfunction in acute stroke (QASC): a cluster randomised controlled trial. Lancet 2011;378(9804):1699-706.
7. Bray BD, Ayis S, Campbell J, et al. Associations between the organisation of stroke services, process of care, and mortality in England: prospective cohort study. BMJ 2013;346:f2827.
8. Saver JL, Fonarow GC, Smith EE, et al. Time to treatment with intravenous tissue plasminogen activator and outcome from acute ischemic stroke. JAMA 2013;309(23):2480-8.

9. Cadilhac DA, Kim J, Lannin NA, et al. National stroke registries for monitoring and improving the quality of hospital care: A systematic review. Int J Stroke 2016;11(1):28-40.

10. Morris S, Hunter RM, Ramsay AI, et al. Impact of centralising acute stroke services in English metropolitan areas on mortality and length of hospital stay: difference-in-differences analysis. BMJ 2014;349:g4757.

11. Turner M, Barber M, Dodds H, et al. Implementing a simple care bundle is associated with improved outcomes in a national cohort of patients with ischemic stroke. Stroke 2015;46(4):1065-70.

12. Hawe P. Lessons from complex interventions to improve health. Annu Rev Public Health 2015;36:307-23.

13. Raine R, Fitzpatrick R, de Pury J. Challenges, solutions and future directions in evaluative research. J Health Serv Res Policy 2016;21(4):215-6.

14. Filipe A, Renedo A, Marston C. The co-production of what? Knowledge, values, and social relations in health care. PLoS Biol 2017;15(5):e2001403.

15. Heaton J, Day J, Britten N. Collaborative research and the co-production of knowledge for practice: an illustrative case study. Implement Sci 2016;11:20.

16. The James Lind Alliance. The James Lind Alliance Guidebook, Version 6. United Kingdom: National Insitute for Health Research; 2016 February Contract No.: Document Number|.

17. Sandercock P, Whiteley W. How to do high quality clinical research 1: first steps. International Journal of Stroke 2017;TBA.

18. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci 2011;6:42.

19. Lauer MS, Gordon D, Wei G, Pearson G. Efficient design of clinical trials and epidemiological research: is it possible? Nat Rev Cardiol 2017;14(8):493-501.

20. Craig P, Cooper C, Gunnell D, et al. Using natural experiments to evaluate population health interventions: new Medical Research Council guidance. J Epidemiol Community Health 2012;66(12):1182-6.

21. Langbein L. Public Program Evaluation: A Statistical Guide: M.E. Sharpe; 2006.

22. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ 2015;350:h1258.

23. Drury P, Levi C, D'Este C, et al. Quality in Acute Stroke Care (QASC): process evaluation of an intervention to improve the management of fever, hyperglycemia, and swallowing dysfunction following acute stroke. Int J Stroke 2014;9(6):766-76.

24. Cadilhac DA, Moloczij N, Denisenko S, et al. Establishment of an effective acute stroke telemedicine program for Australia: protocol for the Victorian Stroke Telemedicine project. Int J Stroke 2014;9(2):252-8.

25. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. Health Serv Res 2013;48(6 Pt 2):2134-56.

26. Purvis T, Moss K, Francis L, et al. Benefits of clinical facilitators on improving stroke care in acute hospitals: a new programme for Australia. Intern Med J 2017;47(7):775-84.

27. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci 2009;4:50.

28. Harvey G, Kitson A. PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. Implement Sci 2016;11:33.

29. Langhorne P, Lewsey JD, Jhund PS, et al. Estimating the impact of stroke unit care in a whole population: an epidemiological study using routine data. J Neurol Neurosurg Psychiatry 2010;81(12):1301-5.

30. Fisher RJ, Cobley CS, Potgieter I, et al. Is Stroke Early Supported Discharge still effective in practice? A prospective comparative study. Clin Rehabil 2016;30(3):268-76.

31. Chouliara N, Fisher RJ, Kerr M, Walker MF. Implementing evidence-based stroke Early Supported Discharge services: a qualitative study of challenges, facilitators and impact. Clin Rehabil 2014;28(4):370-7.

32. Estabrooks CA, Squires JE, Cummings GG, Birdsell JM, Norton PG. Development and assessment of the Alberta Context Tool. BMC health services research 2009;9:234.

33. Cadilhac DA, Andrew NE, Kilkenny MF, et al. Improving quality and outcomes of stroke care in hospitals: protocol and statistical analysis plan for the Stroke123 implementation study. Int J Stroke 2017;accepted 24 July.

34. Cadilhac DA, Andrew NE, Stroil Salama E, et al. Improving discharge care: the potential of a new organisational intervention to improve discharge after hospitalisation for acute stroke, a controlled before-after pilot study. BMJ Open 2017;7(8):e016010.

35. Drummond M, McGuire A, editors. Economic Evaluation in Health Care: merging theory with practice. First ed. New York: Oxford University Press; 2001.

36. Husereau D, Drummond M, Petrou S, et al. Consolidated health economic evaluation reporting standards (CHEERS) statement. Value in Health 2013;16(2).

37. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for

providing translational research informatics support. J Biomed Inform 2009;42(2):377-81.

38. Andrew NE, Sundararajan V, Thrift AG, et al. Addressing the challenges of cross-jurisdictional data linkage between a national clinical quality registry and government-held health data. Aust N Z J Public Health 2016;40(5):436-42.

39. Silverman D. Doing Qualitative Research: A Practical Handbook: Sage Publications; 2000.

40. Patton MQ. Qualitative evaluation and research methods (2nd Ed). Newbury Park: Sage Publications; 1990.

41. Clarke DJ. Using qualitative observational methods in rehabilitation research: Part two. International Journal of Therapy and Rehabilitation 2009;16(8):413-9.

42. Creswell JW, Clark Plano VL. Designing and conducting mixed methods research. 2nd ed. Thousand Oaks, United States: Sage Publications Inc; 2010;488.

43. Purvis T, Cadilhac DA. Observational studies and the chicken and egg issue in stroke. Nat Rev Neurol 2017.

44. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology 2006;3(2):77-101.

45. Shenton AK. Strategies for ensuring trustworthiness in qualitative research projects. Education for Information, 2004;22(2):63-75.

46. Davidoff F, Dixon-Woods M, Leviton L, Michie S. Demystifying theory and its use in improvement. BMJ Quality & Safety 2015;24(3):228-38.

47. Clarke DJ, Godfrey M, Hawkins R, et al. Implementing a training intervention to support caregivers after stroke: a process evaluation examining the initiation and embedding of programme change. Implementation Science 2013;8(1):96.

48. Thurmond VA. The point of triangulation. J Nurs Scholarsh 2001;33(3):253-8.

49. Bagot KL, Cadilhac DA, Vu M, Moss K, Bladin CF, collaborators VST. Telemedicine in the acute health setting: A disruptive innovation for specialists (an example from stroke). J Telemed Telecare 2015;21(8):443-8.

50. Hov MR, Zakariassen E, Lindner T, et al. Interpretation of Brain CT Scans in the Field by Critical Care Physicians in a Mobile Stroke Unit. J Neuroimaging 2017.

51. Sharma R, Fleischut P, Barchi D. Telemedicine and its transformation of emergency care: a case study of one of the largest US integrated healthcare delivery systems. Int J Emerg Med 2017;10(1):21.

52. Hubert GJ, Muller-Barna P, Audebert HJ. Recent advances in TeleStroke: a systematic review on applications in prehospital management and Stroke Unit treatment or TeleStroke networking in developing countries. Int J Stroke 2014;9(8):968-73.

53. Ivers N, Jamtvedt G, Flottorp S, et al. Audit and feedback: effects on professional practice and healthcare outcomes. Cochrane Database of Systematic Reviews 2012(6).

Table 1: Most common study types used in stroke health services research

Type	Application	Designs	Data
Observational/ Quasi-experimental	Investigates changes over time of health service delivery or performance; quantifies impact of a therapeutic intervention or quality improvement approach	Continuous Cohort Cross-sectional Before and after Time-series	Routinely collected clinical data; audit/registry data; prospectively collected quantitative research data
Observational/ Qualitative	Investigates stakeholder behaviour and perspectives of health service delivery	Case study Ethnography	Interviews/ surveys Focus groups Documentary analysis Observation
Mixed-methods	Opportunity to triangulate quantitative and qualitative findings	Behavioural mapping Process evaluation Realist synthesis & evaluation	Observation Time-sampling Interviews/ surveys Focus groups Audit/registry data
Randomised	Measures the effectiveness of an intervention by comparing exposure versus non-exposure in randomised groups	Cluster multi-centre trial Patient-level Step-wedge	Prospectively collected quantitative research data
Economic evaluation	Compares costs and benefits of interventions usually in relation to a comparator	Patient-level Statistical modelling	Prospectively collected quantitative research data Existing research evidence

Table 2: Considerations for establishing a stroke registry or audit program for measuring the quality of care

Attribute	Considerations
Scope	Single site, multisite Population of interest: all stroke, transient ischaemic attack, intracerebral haemorrhage Number of variables and consideration of what is most important to collect as part of a minimum dataset All eligible patients, random sample or consecutive sample Methods of data collection: i.e. paper-based, online database, data linkage of various administrative datasets Duration of follow-up and method (e.g. postal survey, telephone interview, data linkage with death registrations)
Governance	Investigator team Steering or Management Committee with representation from all relevant stakeholders including a consumer representative
Ethics	Local governance and ethical requirements for scope of data collection and subsequent use of the data • Personal information being collected • Patient consent processes for data collection and participation in research (may include opt-in, opt-out, or waiver) • Internal purposes only or data accessed by a third party

	• Data to be used in publications or for secondary purposes
Data custodian	Central entity separate to the participating hospitals that receive and collate the data Coordinating principal investigator Shared data ownership model (individual sites and central entity) and clarity on how data may be used by others
Privacy	Protection and appropriate security for identifiable data if at the patient level in particular ensuring the separation of roles (researchers analysing data are unable to re-identify records) when data linkage studies are performed) Anonymised patient-level data Identification of hospitals
Quality of care feedback procedure	Feedback is most effective when: • there is poor performance to begin with (i.e. there is an opportunity to improve) • the person responsible for the audit and feedback is a supervisor or colleague • feedback is provided more than once • feedback is given both verbally and in writing • feedback includes clear targets and an action plan. (53)

	Examples include: On demand performance reports that can be download directly from the data collection system Individual hospital reports or annual reports (internal only or publically available) where hospitals can identify their performance relative to others (in some countries this may be open review where the hospital is named while in other countries may only use an ID code) Part of a national framework of improvement (national registry or audit program with a focus on particular aspects of care) Active dissemination workshops with a facilitator that then supports an action plan and evidence-based strategy development to overcome modifiable barriers to behaviour change
Funding	Internally resourced or requires external funding Transparency on where the funding has been obtained and role of funder (government, industry, non-government, philanthropy) Ability to maintain the system and or operational personnel