How does variation in assessment and management of dysphagia in acute stroke affect the development of stroke-associated pneumonia (SAP)?

S.A. Eltringham

PhD 2022

How does variation in assessment and management of dysphagia in acute stroke affect the development of stroke-associated pneumonia (SAP)?

SABRINA ARABEL ELTRINGHAM

A thesis submitted in partial fulfilment
of the requirements for
Manchester Metropolitan University
for the Degree of Doctor of Philosophy

Department of Nursing

2022

Table of Contents

Word Count 64,396 excluding the abstract, references and appendix

Table of Tables

Table of Figures

Abstract

Background

Patients with dysphagia are at increased risk of stroke-associated pneumonia (SAP). Preventing SAP is therefore one of the key challenges of stroke unit care. This study investigated how variation in assessment and management of dysphagia in acute stroke affects the risk of stroke patients developing SAP.

Methods

Two systematic reviews identified the methods of dysphagia assessment and management in acute stroke that influence the risk of SAP, and other interventions and care process that may contribute to that risk. A mixed methods study was used to develop a national survey of organisational practice about dysphagia assessment and management in acute stroke. The quantitative method was a review of stroke patient records (N=30). Qualitative methods included interviews with hospital staff (N=15) and patients and carers (N=6). Four topic areas were identified for exploration: (a) dysphagia screening, (b) specialist swallowing assessments and management, (c) NGT feeding, and (d) oral care processes. Speech and Language Therapists from 166 stroke units in England and Wales were surveyed. Survey data were linked to the Sentinel Stroke National Audit Programme (SSNAP) data to estimate risk of SAP.

Results

Survey completion rate was 68% (N=113). There was variation in dysphagia screening protocols (DSPs), oral care and NGT placement. Patterns of consistency occurred in the specialist swallow assessment. Multivariable analyses showed no evidence of association in incidence of SAP when using DSPs that used water only compared to multiple consistencies; when using written guidelines for the specialist swallowing assessment compared to not

using written guidelines; when teams inserted NGTs overnight compared to teams that did not; and when teams had a written oral care protocol compared to those that did not.

Discussion

The multifactorial pathophysiology of SAP and inter dependency of dysphagia care processes make it difficult to unpack which components of dysphagia assessment and management are associated with risk of SAP. Future empirical research and large clinical trials that allow evaluation of multiple interventions to determine what are most effective at minimising risk of SAP are needed.

Declaration

I confirm that all papers submitted in this thesis form original research studies, not submitted in support of application for another degree or qualification.

Open access, permissions and copyright statement

Open Access

The following paper: Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Smith, C. J. and Pownall, S. (2020) 'Factors Associated with Risk of Stroke-Associated Pneumonia in Patients with Dysphagia: A Systematic Review.' Dysphagia, 35(5), Oct, 2019/09/08, pp. 735-744, was published by Springer Nature and is an Open Access article distributed under the terms of the Creative Commons CC BY license, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

The following papers: Eltringham, S. A., Smith, C. J., Pownall, S., Sage, K. and Bray, B. (2019a) 'Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study.' Geriatrics (Basel), 4(4), Oct 25, 2019/11/17, and Eltringham, S. A., Pownall, S., Bray, B., Smith, C. J., Piercy, L. and Sage, K. (2019b) 'Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers.' Geriatrics (Basel), 4(4), Dec 7, 2019/12/11, were published by MDPI under an open access licence. All articles published by MDPI are made immediately available worldwide under an open access license. No special permission is required to reuse all or part of the article published by MDPI, including figures and tables. For articles published under an open access Creative Common CC BY license, any part of the article may be reused without permission provided that the original article is clearly cited.

The following paper: Eltringham, S. A., Bray, B. D., Smith, C. J., Pownall, S. and Sage, K. (2021) 'Are Differences in Dysphagia Assessment, Oral Care Provision, or Nasogastric Tube Insertion Associated with Stroke-Associated Pneumonia? A Nationwide Survey Linked to National Stroke Registry Data.' Cerebrovasc Dis. 2021 Dec 16:1-8, was published by Karger and is Open Access. The authors retain the right to publish the article according to CC BY-NC 4.0 Licence.

Permissions

Permission has been given by the hospital where the case note review took place to include anonymised data from the Clinical Effectiveness Project Report.

Permission has been given by S. Karger AG, Basel to reprint the following paper: Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Pownall, S. and Smith, C. J. (2018) 'Impact of Dysphagia Assessment and Management on Risk of Stroke-Associated Pneumonia: A Systematic Review.' Cerebrovasc Dis, 46(3-4) 2018/09/11, pp. 99-107 as a chapter in the printed and electronic version of this thesis/doctoral dissertation, provided that proper credit will be given to the original source and that S. Karger AG, Basel will be mentioned.

Copyright statement

Acknowledgements

I must first extend my gratitude to my supervisors, *Professor Karen Sage*, *Professor Sue Pownall*, *Professor Craig Smith* and *Dr. Benjamin Bray*. Thank you, *Karen*, for your enthusiasm and unfailing belief in me and your support throughout. Thank you for recommending that I apply for a Stroke Association Post Graduate Fellowship and for building such an expert team around me that significantly contributed to the success and my enjoyment of this project. Your contribution to my development as a researcher has been great. Thank you *Sue* for encouraging me to enter the field of academic study and research, without your unwavering support and tenacity I would not be where I am now. Thank you for your clinical insight and expertise and for asking the 'so what?' questions. Thank you, *Craig* and *Ben,* for generously sharing your specialist knowledge. You encouraged me to develop my skills in ways that I would not have done without your involvement. You have broadened and enriched my doctoral experience, and I will be forever grateful. My thanks also go to *Dr. Karen Kilner* for her statistical expertise in the first year of the project and *Melanie Gee* and *Bea Turpin* for their guidance during the literature searches.

This work was possible due to funding from *The Stroke Association* in the form of a Post Graduate Fellowship, and the *NHS staff* and *people affected by stroke* who participated in this research. I feel immensely privileged to have been part of the Stroke community and I am proud to have carried out research that has been identified as a priority by people affected by stroke.

Final thanks go to my husband *Simon* for his encouragement and loving support, my *peers* and *colleagues* at Sheffield Teaching Hospitals NHS Foundation Trust that enabled me to pursue my research interests, to my mother *Dr. Pauline Booth* who inspired me and paved the way and to my father *John Booth* for his unconditional love and belief in me.

Chapter 1 Introduction

Introduction

This chapter introduces the researcher and their core values and provides an overview of the problem being investigated. The chapter outlines the research aims and research question and sets out the programme of work involved. The chapter introduces key pillars which underpin the research; specifically the use of data from the Sentinel Stroke National Audit Program (SSNAP) and how people affected by stroke were involved in the research process. It sets out the format and structure of the thesis.

1.1 The Author

My name is Sabrina Eltringham. I am a speech and language therapist working in Sheffield Teaching Hospitals NHS Foundation Trust. I applied for funding to undertake a PhD which was awarded by the Stroke Association with a Post Graduate Fellowship (TSA PGF 2017/03) in June 2017. I undertook the PhD part time. My decision to remain working clinically throughout my PhD was driven by wanting to remain embedded within clinical practice and stay in tune with the changing dynamics of acute stroke services. I also wanted to publish the results of the research contemporaneously in order that the knowledge could be applied to the clinical setting for the improvement of stroke services and stroke patient outcomes. Ensuring that people affected by stroke are involved in the research process is a core value of mine and fundamental to the research.

1.2 Research background

1.2.1 Stroke-associated pneumonia (SAP)

Common classifications of pneumonia in the clinical setting include Community Acquired Pneumonia (CAP) and Hospital Acquired Pneumonia (HAP). Both depend on the 48-hour mark pre and post admission to hospital. CAP refers to patients who present to hospital with pneumonia and up to 48 hours into a hospital stay whereas HAP refers to those patients who develop pneumonia more than 48 hours after admission to hospital. The term stroke-associated pneumonia was created by the Pneumonia in Stroke Consensus (PIECES) Group (Smith et al., 2015) to define any lower respiratory infection within the first 7 days of admission of stroke. One of the reasons for this differentiation is the pathophysiology involved.

1.2.1.1 Pathophysiology of SAP

The pathophysiology of SAP is multifactorial. Infection may precede and develop post stroke. Current theories propose a complex interaction between an “infectious reservoir (oral bioburden, nasopharynx, upper gastrointestinal tract, exposure to hospital pathogens), mechanism for delivery to the lower respiratory tract (dysphagia, impaired cough reflex, reduced level of consciousness), and impaired host immune responses (stroke-induced immune suppression)” (Elkind et al., 2020).

The microbiological aetiology of SAP, CAP and HAP overlap. A substantial proportion of SAP is poly microbial (Smith, 2020) and may evolve with organisms typical of both CAP and HAP indicative of preceding and post stroke pneumonia. In a systematic review (Kishore et al., 2018) of the organisms that cause stroke-associated pneumonia, aerobic Gram-negative bacilli (e.g. Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa) and Gram-positive cocci (e.g.

Staphylococcus aureus and Streptococcal pneumoniae) were associated with the majority of SAP.

1.2.1.2 Risk factors associated with SAP

Stroke-associated pneumonia occurs in 14% of patients (Kishore et al., 2015) and is associated with increased risk of mortality, immobilisation, general frailty and delay in rehabilitation (Westendorp et al., 2011). There are established clinical risk factors associated with increased odds of developing SAP. Dysphagia exhibits a strong association (OR 3.53 (2.69-4.64)), with age (OR 1.07 (1.04-1.11)), National Institutes of Health Stroke Scale (NIHSS) (OR 1.07 (1.05-1.09)) and diabetes OR 1.15 ((1.08-1.23)) being consistent predictors but exhibiting weaker associations (Wästfelt et al., 2018).

Chaves et al. (2022) explored the variation in SAP between stroke units in England and Wales. The median SAP prevalence was 8.5% (IQR 6.1-11.5%) with a maximum of 21.4%. Clinical characteristics were found to account for only 5% of the variation, suggesting that other factors contribute to the observed variation, for example diagnostic approaches to SAP and stroke care processes. The impact of these clinical care processes on the development of SAP in stroke survivors is uncertain.

The susceptibility to post stroke pneumonia within the first 72 hours of stroke has considerable implications for therapeutic preventive intervention. Preventing SAP requires very early intervention strategies after stroke onset to have a pathophysiological and clinical impact, particularly as clinical manifestations of SAP lag actual evolution (Smith, 2021).

1.2.2 Dysphagia and Stroke-associated pneumonia

Dysphagia is a strong predictor of SAP and, in patients who aspirate, risk increases 11-fold (Martino et al., 2005). Preventative measures to identify dysphagia and reduce aspiration such as early dysphagia screening and specialist assessment by a speech and language therapist are associated with reduced risk of SAP (Bray et al., 2017). Up to half of patients with SAP do not aspirate (Westendorp et al., 2011) and there is potential for a range of medical interventions and care processes that may influence incidence of SAP during acute phase stroke in patients with dysphagia.

1.3 Research aims, question and programme of work

1.3.1 Research aims

The primary aim of the programme of work was to find out how methods of dysphagia assessment and clinical management during the first 72 hours of admission to hospital affect the risk of stroke patients developing stroke-associated pneumonia (SAP). A second aim was to find out what care processes and interventions, specific to patients with dysphagia affect the risk of stroke patients developing SAP during acute phase stroke.

1.3.2 Research question

How does variation in assessment and management of dysphagia in acute stroke affect the development of stroke-associated pneumonia (SAP)?

1.3.3 Programme of work

The overall programme comprised of two systematic reviews of the literature (Phase 1), a mixed methods study (Phase 2) and a quantitative study (Phase 3) as shown in Figure 1.1.

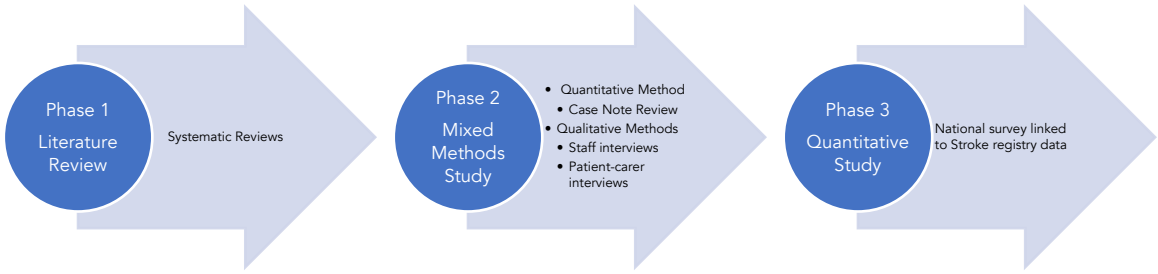


Figure 1.1: Programme of work

The two systematic reviews (Eltringham et al., 2018; Eltringham et al., 2020) (Phase 1) provide the theoretical underpinnings to the research topic by summarising current evidence on methods of assessment. They enabled refinement of the research aims by defining more clearly the medical interventions and clinical care processes that may impact on SAP. The systematic reviews combined with the recommendations from the Royal College of Physicians (RCP) Clinical Guideline for Stroke (ISWP, 2016b) informed the data collection tool for a single site case note review of stroke patients' medical records. The case notes came from patients who were screened and assessed for dysphagia on admission to hospital. The reviews and RCP guideline also informed the topic guide for an interview study with staff involved in the assessment and management of dysphagia and a study exploring the experiences of stroke patients who had their swallowing assessed during their first 72 hours of admission to hospital.

The case note review provided detailed understanding of dysphagia management during the first 72 hours from admission while the interviews provided insights into current practice, information not readily available

from quantitative data (Phase 2). The results of the interviews (Eltringham et al., 2019a; Eltringham et al., 2019b) and case note review were integrated in order to inform a national survey sent out to SLT Clinical Leads in Acute Stroke in hyper/acute stroke units (H/ASU) in hospitals in England and Wales (Phase 3). The results of the survey were statistically analysed and linked with data from the SSNAP register to explore variation in organisational practice and incidence of stroke-associated pneumonia.

1.4 Philosophical assumptions

This programme of work makes claims for knowledge, based on cause and effect thinking, the focus and measurement of selected variables and the testing of theories. The hypotheses and selected variables are presented in the statistical analysis plan in Chapter 6. The philosophical approach is shaped by a Postpositivist worldview. Postpositivism is an extension and adaptation of the ideas of its predecessor Positivism. The ontology of Postpositivism (i.e. What constitutes reality?) is that reality exists but there may be limits to our ability to accurately measure it. This ties into Post positivist epistemology (i.e. How do we know what we know?) which is that the researcher is building an approximation of the object of research but never quite an absolute truthful picture of it. A part of the underlying rationality of Postpositivism is the idea of falsifiability. The axiology and values (i.e. What gives things value and what do we value?) of Postpositivism is reason, the value set is neutral and takes an unbiased position to what is being observed. The methodology (i.e. How knowledge is gained) of Postpositivism is rigourously defined and the rhetoric used is formal style where researchers use agreed-upon definitions of variables. For this study, the term stroke-associated pneumonia is based on the recommendations from the Pneumonia in Stroke Consensus Group (PIECES) (Smith et al. 2015) and SAP incidence is defined as prescription of antibiotics for a newly diagnosed pneumonia within the first 7 days of a person's admission for stroke and is based on data recorded on the SSNAP register. This definition of SAP

was chosen to be consistent with what is reported on the SSNAP register and what has been previously used to analyse risk of SAP in stroke units in England and Wales (Bray et al., 2017; Chaves et al., 2022). SSNAP only records clinically diagnosed pneumonia treated with antibiotics, which is not necessarily the same as “clinical diagnosis of pneumonia” (as some patients with clinically diagnosed pneumonia may not have received antibiotics, for example, when approaching end of life, when active treatment may not be deemed appropriate).

1.5 Sentinel Stroke National Audit Program (SSNAP) registry data

The Sentinel Stroke National Audit Program (SSNAP) is a large health data registry that was used as a data resource to prepare material for Phase 2 and Phase 3 of the programme of research including: Case Note Review (Phase 2); Staff Interviews (Phase 2) and the national survey (Phase 3).

1.5.1 Introduction to SSNAP

The Sentinel Stroke National Audit Programme (SSNAP) is a United Kingdom healthcare quality improvement programme commissioned by the Healthcare Quality Improvement Partnership (HQIP) and represents 90% of all stroke hospital admissions in England, Wales and Northern Ireland. SSNAP audits the care provided for patients during and after they receive inpatient care following a stroke. Data are submitted from hospitals on care processes which a patient is recommended to receive and measures the interventions against standards based on the latest clinical guidelines (ISWP, 2016b; NICE, 2019). Follow up data are also collected, including disability outcomes at hospital discharge and at six months, using standardised assessment scales e.g. Modified Rankin Scale (Fish, 2011), enabling measurement of the impact of hospital care processes on longer term outcomes.

1.5.2 Using the SSNAP register as big data for research purposes

Large data resources such as SSNAP generate statistical power and provide opportunities for clinical areas like dysphagia, to build the evidence base for clinical practice which can be difficult to evaluate in randomised controlled trials. They also reflect the reality of patients and clinical practice. One of the challenges of using these data is that they are not collected specifically for research purposes and may require adjustments to make it research ready. The vastness of the data set also requires the researcher to sift through the data to find the relevant data for the purpose of the research and thoroughly understand the types of data and the definitions within it. Another challenge is that the data are dynamic and fast moving and are not generated in controlled conditions such as clinical trials or experiments. The data respond to changes in the clinical landscape and world events, such as a global pandemic, which can make the data messy and there may be missing data.

1.5.3 SSNAP Key performance indicators

In the first stage of hyper acute care, there are specific specialist assessment standards. These include whether patients receive a dysphagia screen within 4 hours of admission, a formal swallowing assessment within 72 hours of admission, and measurement of medical interventions, including the prescription of antibiotics for a newly acquired pneumonia within the first 7 days of hospital admission. The collection of standardised data and auditing of key performance indicators across multiple domains allows comparison to be made. It can reveal variations in organisation practice and their impact on outcomes across multiple hospitals and can help to identify targets for improvement.

1.6 Patient and Public Involvement (PPI) throughout this programme of work

Patient and Public Involvement (PPI) in research may be at any stage during the research process. It may include, for example, contributing to prioritising the research questions, applying for funding and ethical approval, offering advice as members of a project advisory group, providing feedback on participant research materials, or undertaking interviews with research participants or disseminating the research findings. Figure 1.2 presents the ways that people can be involved in research.

Figure 1.2 Ways that patients and the public can be involved in the research cycle

Patients and the public (also referred to in this thesis as service users and people affected by stroke) were actively involved in different stages of the research project. These include; prioritising the research question (Chapter 1.6.1); developing the protocol for the programme of work to

address the research question (Chapter 1.6.2), analysis and interpretation of the data (Chapter 4.3.1) and the dissemination of the research *(*Chapter 4.3.2).

1.6.1 Prioritising the research question

The thesis question aligns to the three groups of interested parties: the Royal College of Speech and Language Therapists (RCSLT), the National Institute of Health Research (NIHR) and the Stroke Association. The Stroke Association worked with people affected by stroke and care professionals to establish priority areas for research across the stroke pathway, using the James Lind Alliance method (JLA, 2021). The JLA process involves bringing patients, carers, and clinicians together to jointly identify priorities for research. The question 'How can complications of stroke be reduced e.g. pneumonia?' was identified as a Top 10 research question in the priority area 'Stroke prevention, diagnosis, prehospital and hospital care'. The RCSLT/NIHR similarly worked with the JLA process, to identify and prioritise areas for dysphagia adult research (Longhurst, 2018). Carrying out research that has been jointly identified by people affected by stroke and health professionals as a priority means that it is clinically relevant and has the potential to make the greatest difference to the lives of people affected by stroke.

1.6.2 Developing the protocol for the programme of work to address the research question

The Therapeutics and Palliative Care research panel is a hospital Patient and Public Involvement (PPI) group that is within Sheffield Teaching Hospitals NHS Foundation Trust. The group is made up of people who have either direct patient experience or indirect experience as a carer, of a range of diagnostic, rehabilitation and palliative care services (Gordon et al., 2018). Some members have been affected by stroke. Their involvement ensured that the protocol layperson title and abstract were easily understandable. Based on their feedback, further considerations

were made about how to reduce the risk of participant bias in staff interviews by broadening the staff groups and host institutions where the interviews took place. A major change made to the protocol following specific feedback was to include the patient and carer perspectives which had not been part of the original research plan. The group also provided additional suggestions about how service users could be further involved in the dissemination of the research. The PPI group enriched the study by giving a service user perspective on the study design. This included ethical considerations such as when to approach participants and best ways to engage with them.

1.7 Structure of the Thesis

Five published papers (Eltringham et al., 2018; Eltringham et al., 2020; Eltringham et al., 2019a; Eltringham et al., 2019b; Eltringham et al., 2021) have been written and are presented in journal article style (Chapter 2 Literature Review, Chapter 4 Mixed Methods Study and Chapter 6 Survey Results), except for the formatting of the headings which has been adapted for consistency, and the reference lists which have been merged with the thesis bibliography.

Some of the methods and results underlying the published papers are expanded upon in Chapters 3 (3.4), Chapter 5 (5.1) and Chapter 6 (6.1) so that the thesis reader has a fuller understanding of the methods used where journal word limits prevent a more detailed summary.

1.7.1 Chapter synopses and abstracts from contributing published papers

1.7.1.1 **Chapter 2. Literature Review** includes two published systematic reviews (Eltringham et al., 2018; Eltringham et al., 2020) and an additional unpublished summary of relevant evidence since their publication.

Paper 1

Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Pownall, S. and Smith, C. J. (2018) 'Impact of Dysphagia Assessment and Management on Risk of Stroke-Associated Pneumonia: A Systematic Review.' *Cerebrovasc Dis*, 46(3-4) 2018/09/11, pp. 99-107.

Abstract

Background

Patients with dysphagia are at an increased risk of stroke-associated pneumonia. There is wide variation in the way patients are screened and assessed during the acute phase. The aim of this review was to identify the methods of assessment and management in acute stroke that influence the risk of stroke-associated pneumonia. Studies of stroke patients that reported dysphagia screening, assessment or management and occurrence of pneumonia during acute phase stroke were screened for inclusion after electronic searches of multiple databases from inception to November 2016. The primary outcome was association with stroke-associated pneumonia.

Summary

Twelve studies of 87,824 patients were included. The type of dysphagia screening protocol varied widely across and within studies. There was limited information on what comprised a specialist swallow assessment and alternative feeding was the only management strategy, which was reported for association with stroke-associated pneumonia. Use of a formal screening protocol and early dysphagia screening (EDS) and assessment by a speech and language pathologist (SLP) were associated with a reduced risk of stroke-associated pneumonia. There was marked heterogeneity between the included studies, which precluded meta-analysis.

Key Messages

There is variation in the assessment and management of dysphagia in acute stroke. There is increasing evidence that EDS and specialist swallow assessment by an SLP may reduce the odds of stroke-associated pneumonia. There is the potential for other factors to influence the incidence of stroke-associated pneumonia during the acute phase.

Paper 2

Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Smith, C. J. and Pownall, S. (2020) 'Factors Associated with Risk of Stroke-Associated Pneumonia in Patients with Dysphagia: A Systematic Review.' Dysphagia, 35(5), Oct, 2019/09/08, pp. 735-744.

Abstract

Dysphagia is associated with increased risk of stroke-associated pneumonia (SAP). However, it is unclear what other factors contribute to that risk or which measures may reduce it. This systematic review aimed to provide evidence on interventions and care processes associated with SAP in patients with dysphagia. Studies were screened for inclusion if they included dysphagia only patients, dysphagia and non-dysphagia patients or unselected patients that included dysphagic patients and evaluated factors associated with a recorded frequency of SAP. Electronic databases were searched from inception to February 2017. Eligible studies were critically appraised. Heterogeneity was evaluated using I^2. The primary outcome was SAP. Eleven studies were included. Sample sizes ranged from 60 to 1088 patients. There was heterogeneity in study design. Measures of immunodepression are associated with SAP in dysphagic patients. There is insufficient evidence to justify screening for aerobic Gram-negative bacteria. Prophylactic antibiotics did not prevent SAP and proton pump inhibitors may increase risk. Treatment with metoclopramide may reduce SAP risk. Evidence that nasogastric tube (NGT) placement increases risk of SAP is equivocal. A

multidisciplinary team approach and instrumental assessment of swallowing may reduce risk of pneumonia. Patients with impaired mobility were associated with increased risk. Findings should be interpreted with caution given the number of studies, heterogeneity and descriptive analyses. Several medical interventions and care processes, which may reduce risk of SAP in patients with dysphagia, have been identified. Further research is needed to evaluate the role of these interventions and care processes in clinical practice.

1.7.1.2 **Chapter 3. Methodologies underpinning the construction of the national survey** sets out the justification for the number of small studies which make up the preparation work for the national survey composition. It also provides detail on the adaptation of Sentinel Stroke National Audit Programme data for this part of the programme of work.

1.7.1.3 **Chapter 4. Results of the underpinning studies** describes the results of the work which underpinned the construction of the national questionnaire. It includes a summary of the clinical audit data and two published papers reflecting the two interview studies, one of health care workers and the other from users of the service (Eltringham et al., 2019a; Eltringham et al., 2019b).

Paper 3

Eltringham, S. A., Smith, C. J., Pownall, S., Sage, K. and Bray, B. (2019a) 'Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study.' *Geriatrics (Basel)*, 4(4), Oct 25, 2019/11/17.

Abstract

(1) Background: Patients with dysphagia are at increased risk of stroke-associated pneumonia. There is wide variation in the way patients are screened and assessed. The aim of this study is to explore staff opinions

about current practice of dysphagia screening, assessment and clinical management in acute phase stroke. (2) Methods: Fifteen interviews were conducted in five English National Health Service hospitals. Hospitals were selected based on size and performance against national targets for dysphagia screening and assessment, and prevalence of stroke-associated pneumonia. Participants were purposefully recruited to reflect a range of healthcare professions. Data were analysed using a six-stage thematic process. (3) Results: Three meta themes were identified: delays in care, lack of standardisation and variability in resources. Patient, staff, and service factors that contribute to delays in dysphagia screening, assessment by a speech and language therapist, and delays in nasogastric tube feeding were identified. These included admission route, perceived lack of ownership for screening patients, prioritisation of assessments and staff resources. There was a lack of standardisation of dysphagia screening protocols and oral care. There was variability in staff competences and resources to assess patients, types of medical interventions, and care processes. (4) Conclusion: There is a lack of standardisation in the way patients are assessed for dysphagia and variation in practice relating to staff competences, resources and care processes between hospitals. A range of patient, staff and service factors have the potential to impact on stroke patients being assessed within the recommended national guidelines.

Paper 4

Eltringham, S. A., Pownall, S., Bray, B., Smith, C. J., Piercy, L. and Sage, K. (2019b) 'Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers.' *Geriatrics (Basel)*, 4(4), Dec 7, 2019/12/11.

Abstract

(1) Background: Swallowing difficulties (dysphagia) after stroke are not uncommon and is a consistent risk factor for stroke-associated

pneumonia. This interview study explores the perspectives of stroke survivors, who had their swallowing assessed in the first few days of admission to hospital, and their informal caregivers. (2) Methods: A participatory approach was used involving people affected by stroke in the interpretation and analysis of the interview data. Data was thematically analysed and six themes were identified. (3) Results: These themes included how past-future experiences may influence a person's emotional response to events; understanding what is happening and adjustment; the impact of dysphagia; attitudes to care; communication to patients and procedural issues. (4) Conclusion: The findings highlight the importance of effective public health messages to improve people's responsiveness to the signs of stroke, standardisation of assessment and management procedures, effective communication to patients about the consequences of dysphagia, and the impact of dysphagia on the person who had the stroke and their informal caregiver.

1.7.1.4 **Chapter 5. Survey Design Methodology** provides detail on the approach taken towards the integration and interpretation of the quantitative and qualitative data from the mixed methods study and the formulation of the survey questions. The chapter sets out the rationale for the quantitative study and method of data collection, the implementation of social exchange theory and what steps were taken to minimise potential sources of survey error. The chapter describes the process of building the survey on the online survey platform Qualtrics, the testing of the survey and the ramifications of the COVID-19 pandemic.

1.7.1.5 **Chapter 6. Survey Results** includes the statistical analysis plan and the published paper about the survey results (Eltringham et al., 2021).

Paper 5

Eltringham, S.A., Bray, B.D, Smith C.J., Pownall S., Sage K. 'Are Differences in Dysphagia Assessment, Oral Care Provision, or Nasogastric Tube Insertion Associated with Stroke-Associated Pneumonia? A Nationwide Survey Linked to National Stroke Registry Data.' Cerebrovasc Dis. 2021 Dec 16:1-8. doi: 10.1159/000519903. Epub ahead of print. PMID: 34915473.

Abstract

Introduction

Stroke-associated pneumonia (SAP) is a common complication associated with poor outcomes. Early dysphagia screening and specialist assessment is associated with a reduced risk of SAP. Evidence about oral care and nasogastric tube (NGT) placement is equivocal. This study aimed to expose variations in dysphagia management practices and explore their associations with SAP.

Participants and Methods

Speech pathologists from 166 stroke units in England and Wales were surveyed about dysphagia assessment and management, oral care, and NGT placement. Survey data were then linked to the Sentinel Stroke National Audit Programme (SSNAP), the national register of stroke. Univariable and multivariable linear regression models were fitted to estimate the association between dysphagia management practices and SAP incidence.

Results

113 hospitals completed the survey (68%). Variation was evident in dysphagia screening protocols (DSPs), oral care, and NGT practice while specialist swallow assessment data patterns were more consistent. Multivariable analysis showed no evidence of an association in incidence of SAP when using a water-only hospital DSP compared to a

multiconsistency DSP (B −0.688, 95% CI: −2.912 to 1.536), when using written swallow assessment guidelines compared to not using written guidelines (B 0.671, 95% CI: −1.567 to 2.908), when teams inserted NGTs overnight compared to teams which did not (B −0.505, 95% CI: −2.759 to 1.749), and when teams had a written oral care protocol compared to those which did not (B −1.339, 95% CI: −3.551 to 0.873).

Discussion and Conclusion

Variation exists in dysphagia screening and management, but there was no evidence of an association between clinical practice patterns and incidence of SAP. Further research with larger sample sizes is needed to examine association with SAP.

1.7.1.6 **Chapter 7 Discussion** is written in an editorial style. It begins with an overview of the research problem addressed and provides a summary of the different study designs that were used as part of the overall programme of research. The challenges of identifying which components of dysphagia assessment and management are associated with risk of SAP are discussed. Potential limitations of the research, implications for clinical practice followed by suggestions for future research directions are presented.

Chapter 2 Literature Review

Introduction

This chapter presents the theoretical background for the programme of research. It includes two systematic reviews which evaluated the evidence relevant to the two research aims. The first systematic review asks: 'How do methods of dysphagia assessment and clinical management during the first 72 hours of admission to hospital affect the risk of stroke patients developing stroke-associated pneumonia (SAP)'? The second asks: 'What care processes and interventions specific to patients with dysphagia affect the risk of stroke patients developing SAP during acute phase stroke'? Finally, the chapter concludes with an updated summary of the relevant evidence since their publication. This section used the same search methods as the two papers and includes results relevant to the research questions/aims.

2.1 Impact of Dysphagia Assessment and Management on Risk of Stroke-Associated Pneumonia: A systematic review

Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Pownall, S. and Smith, C. J. (2018) 'Impact of Dysphagia Assessment and Management on Risk of Stroke-Associated Pneumonia: A Systematic Review.' *Cerebrovasc Dis*, 46(3-4) 2018/09/11, pp. 99-107.

2.1.1 Introduction

Stroke-Associated Pneumonia (SAP) incorporates the spectrum of lower respiratory tract infections within the first 7 days after stroke onset (Smith et al., 2015). It is one of the most common post-stroke infections, affecting 14% of patients (Kishore et al., 2015), and is associated with an increased risk of hospital mortality (Westendorp et al., 2011), prolonged hospital stay (Finlayson et al., 2011) and associated healthcare costs (Katzan et al., 2007). The timing of SAP reflects the complex relationship

between infection and inflammatory responses, which may precede and develop post stroke. Respiratory infections frequently trigger ischemic stroke and worsen in the days that follow (Emsley and Hopkins, 2008). Brain-induced immunodepression and aspiration related to impaired consciousness and dysphagia (Hannawi et al., 2013) increase vulnerability to SAP in the acute phase after stroke.

Incidence of dysphagia in stroke patients varies widely depending on patient characteristics, variations in study design, type and severity of stroke, time of assessment and diagnostic techniques (Martino et al., 2005). In acute stroke, the incidence ranged between 37 and 78% depending on the assessment method; lower incidence was detected using an initial screening test (37–43%) compared to clinical assessments (30–55%) and videofluoroscopy (VFS; 64–78%) (Martino et al., 2005).

Early identification of dysphagia post stroke informs decisions regarding nutritional management and may reduce pulmonary complications. Multiple national and international guidelines (ISWP, 2016b; Jauch et al., 2013; Casaubon et al., 2015; informme.org, 2017; ESO, 2008) recommend that people with acute stroke have their swallow screened by an appropriately trained healthcare professional, using a validated screening tool and remain nil by mouth (NBM) until a swallow screen is completed. The recommended time from admission to screen ranges from within 4 (ISWP, 2016b; informme.org, 2017) to 24 h (Casaubon et al., 2015). If dysphagia is suspected, the person should be referred to a healthcare professional with expertise in swallowing to have a specialist assessment. This usually comprises a cranial nerve examination, trials of different diet and fluid textures and compensatory strategies. Those with suspected aspiration should be reassessed for instrumental examination using techniques such as VFS or Flexible Endoscopic Evaluation of Swallowing (FEES) (ISWP, 2016b; Jauch et al., 2013). Results from these assessments inform management which may include: NBM with

alternative nutrition if swallowing is unsafe, diet or fluid modification, compensatory strategies or muscle strengthening exercises.

There is a wide variation in dysphagia screening protocols (DSP) and no consensus exists on the optimal DSP (Daniels et al., 2012). Most speech and language pathologists (SLPs) apply their clinical reasoning to tailor their bedside assessment over using a standardised assessment (McAllister et al., 2016) such as the Mann Assessment of swallowing ability (Mann, 2002). To complicate matters further, the terminology describing DSPs and bedside clinical assessments is often used inconsistently and interchangeably (informme.org, 2017).

The aim of this systematic review was to answer the question “How do methods of dysphagia screening, assessment and management during the first 72 h of admission affect the risk of SAP?” The objective was to identify the methods that influence the risk of SAP. A search of the National Institute for Health Research Centre for Reviews and Dissemination Database (NIHR CRD, 2017) was undertaken to check whether there were existing or ongoing reviews, which addressed this question.

2.1.2 Methods

2.1.2.1 Search Strategy and Selection Criteria

A systematic review was undertaken according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement and Centre for Reviews and Dissemination guidance (Moher et al., 2009; CRD, 2009). A building block (Booth, 2008) approach identified search terms for each concept which were added using the Boolean AND operator. Two search strategies were used to develop the search terms; National Clinical Guideline for Stroke (ISWP, 2016b) and the PISCES (Pneumonia in Stroke Consensus) Group (Smith et al. 2015). Co-authors (S.P., K.S., and M.G.) reviewed the search strategy (online suppl. Appendices; for all

online suppl. material, see www.karger.com/doi/10.1159/000492730). Electronic databases were searched from inception for relevant studies: CINAHL (via EBSCOhost to 19/11/16), COCHRANE (via Wiley Online to 23/11/16), EMBASE (via NICE Healthcare Databases to 23/11/16), MEDLINE (via EBSCOhost to 19/11/16) and SCOPUS to 23/11/16. In addition, references and citations of included studies were screened.

The review was restricted to peer-reviewed English language stroke research, which evaluated dysphagia screening, assessment or management within the first 72 h of admission to hospital, and recorded frequency of SAP. The time restriction of ≤ 72 h might not be explicit in the title/abstract; therefore, if the abstract met all the other inclusion criteria, it was included in the next stage of the screening process. Non-stroke or mixed population, studies of exclusively intubated and mechanically ventilated patients or where dysphagia assessment or management was beyond 72 h were excluded and studies not documenting SAP or pneumonia post stroke or pre-existing pneumonia were also excluded.

Two authors independently applied the inclusion/exclusion criteria to titles and abstracts for eligibility (online suppl. Appendices). Differences were forwarded to a third author for consensus. Abstracts that met the inclusion criteria were recommended for full-text reading. S.A.E., S.P., and K.S. screened 10% of articles recommended and any differences were agreed by consensus. S.A.E. assessed remaining articles.

2.1.2.2 Data Abstraction and Analysis

S.A.E. piloted and designed a data extraction form base on Royal College of Physicians National Clinical Guideline for Stroke (ISWP, 2016a) and independently extracted data for the titles. Data extraction included study design and baseline characteristics of the population, as well method of screening, assessment and management, rate and association with pneumonia (online suppl. Appendices). Quality Assessment tools (CASP,

2017; NHLBI, 2017) were used to appraise the studies for risk of bias (online suppl. Appendices).

2.1.2.3 Statistical Analysis

Inter-rater reliability was analysed using the Kappa statistic. Heterogeneity was evaluated using random effects models (DerSimonian and Laird, 2015). Given that substantial heterogeneity was expected, further meta-analysis was not anticipated. Microsoft Excel produced forest plots for illustration only (Neyeloff et al., 2012).

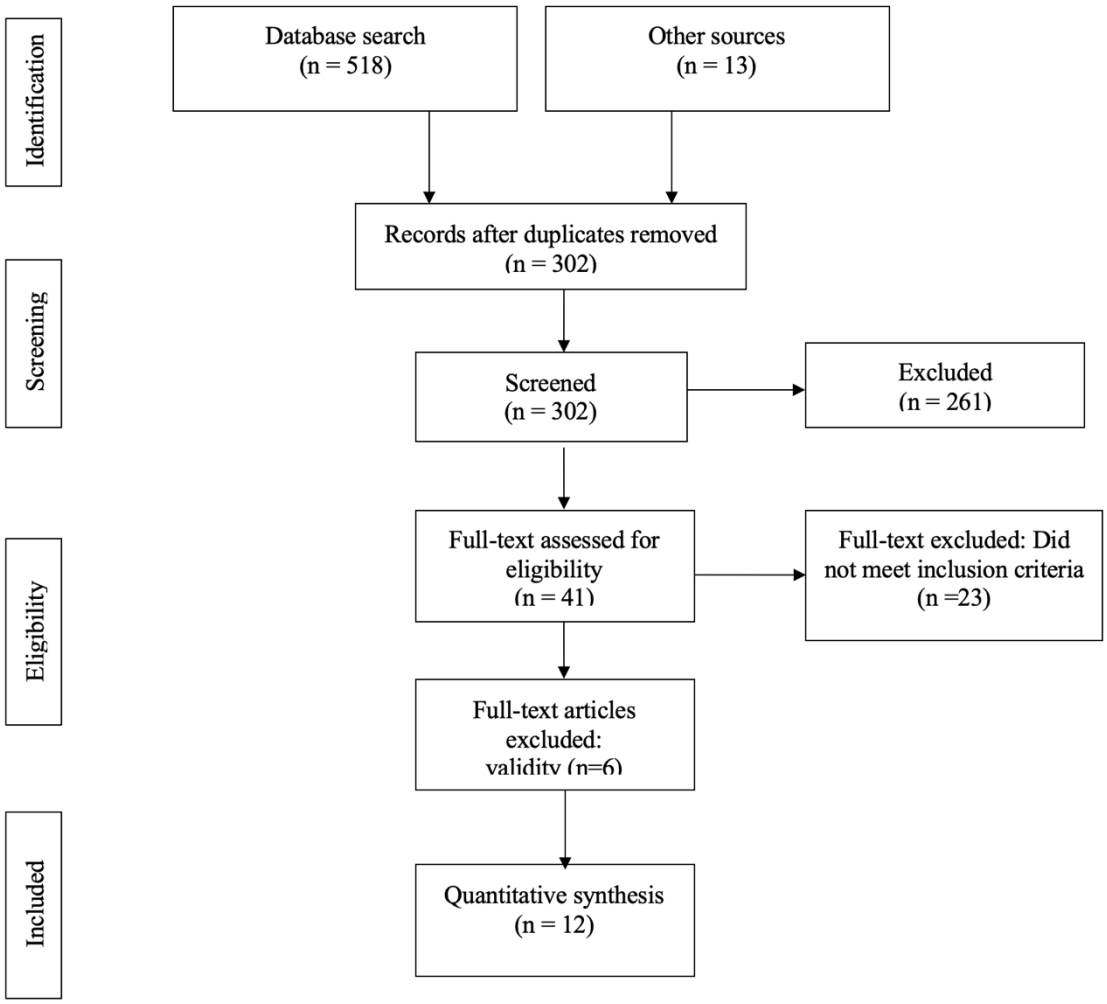
2.1.3 Results

Searching databases yielded 518 references and 13 arose through other sources (Fig. 2.1). Inter-rater reliability for the inclusion/exclusion criteria was .71. Forty-one full-text articles were assessed for eligibility. Twelve studies with a total of 87,824 ischaemic and haemorrhagic stroke patients were included (Fig 2.1). The majority were prospective observational studies, of which 5 were registry based (Al-Khaled et al., 2016; Arnold et al., 2016; Bray et al., 2017; Hinchey et al., 2005; Joundi et al., 2017). Two used a quasi-experimental design (Palli et al., 2017; Perry and McLaren, 2000); and post-intervention data are reported (Table. 2.1). There was one retrospective review (Hoffmeister et al., 2013). Europe (Al-Khaled et al., 2016; Arnold et al., 2016; Bray et al., 2017; Palli et al., 2017; Perry and McLaren, 2000; Smithard et al., 1996) hosted 50% of studies, United States 25% (Hinchey et al., 2005; Odderson et al., 1995; Odderson and McKenna, 1993) and the remainder were in Chile (Hoffmeister et al., 2013), Japan (Maeshima et al., 2014) and Canada (Joundi et al., 2017). Stroke severity was reported in 7 studies using the National Institutes of Health Stroke Scale. There was variation in the way participant characteristics such as age and the National Institutes of Health Stroke Scale were reported and missing information, which precluded doing any summary statistics. One study (Bray et al., 2017) accounted for 72% of the combined population of studies, making

measurement of mean statistically inappropriate. Marked variation in study design, reporting of participant characteristics and the dominance of one study prohibited meta-analysis.

Most studies controlled selection bias by consecutive recruitment of patients that met eligibility criteria and screening of all patients on admission (Al-Khaled et al., 2016; Arnold et al., 2016; Bray et al., 2017; Hinchey et al., 2005; Joundi et al., 2017; Palli et al., 2017; Perry and McLaren et al., 2000; Odderson et al., 1995; Odderson and McKenna, 1993). There was still potential for bias dependent on the actual rate of screening. One study screened only patients considered at risk of dysphagia (Hoffmeister et al., 2013), while in another, it was unclear how the cohort was recruited (Maeshima et al., 2014). Performance bias is also likely to have influenced reported findings. Potential risk for measurement bias exists because of heterogeneity in methods of dysphagia intervention, and variation in the way SAP was diagnosed. The criterion for determining the reliability of results ranged from levels of significance only ($p \leq 0.05$) (Palli et al., 2017), to OR (Al-Khaled et al., 2016; Hinchey et al., 2005; Maeshima et al., 2014), and adjusted OR (aOR) (Bray et al., 2017; Joundi et al., 2017; Hoffmeister et al., 2013). The confidence intervals for the association between dysphagia screening and SAP in the Chilean (Hoffmeister et al., 2013) and Japanese (Maeshima et al., 2014) studies (online suppl. Appendices) suggested uncertainty about the precision of the results.

Fig. 2.1. Search methodology and outcome



2.1.3.1 Type and Methods of Dysphagia Screening

Three studies reported more than one type of screening method involving a combination of informal, formal and standardised assessments (Hinchey et al., 2005; Joundi et al., 2017; Perry and McLaren, 2000). The Toronto Bedside Swallowing Screening Test was most frequently used in the Canadian registry-based study (Joundi et al., 2017). Perry and McLaren found the Standardised Swallow Assessment (SSA) was the most common method in their post-test group (Perry and McLaren, 2000). Two studies used the Gugging Swallow Screen (GUSS) (Arnold et al., 2016; Palli et al., 2017). Smithard et al. (Smithard et al., 1996) used their own validated Bedside Swallow Assessment. Maeshima et al. (Maeshima et al., 2014) used a repetitive saliva swallow test and modified water test. Two studies used locally developed screens (Al-Khaled et al., 2016; Odderson et al., 1995) and 2 did not describe the screening process or specify the DSP (Hoffmeister et al., 2013; Odderson and McKenna, 1993). In the largest study, the dataset lacked information on the nature of the DSP used (Bray et al., 2017).

Screening was undertaken by nurses, physicians and physiotherapists with special training in dysphagia and SLPs. Methods of screening followed a stepwise procedure, which began with an indirect swallowing test or risk assessment followed by a direct swallow assessment with water and, in some studies, diet consistencies. Four studies involved an indirect and a direct swallow test with water only (Hinchey et al., 2005; Perry and McLaren, 2000; Smithard et al., 1996; Maeshima et al., 2014); this is consistent with the Toronto Bedside Swallowing Screening Test (Joundi et al., 2017). One study involved only direct assessment with water and/or thickened apple juice and an additional swallowing and cough provocation test to detect for silent aspiration (Al-Khaled et al., 2016). The GUSS involves an indirect and direct swallow assessment with water, semi-solid and solid diet consistencies (Arnold et al., 2016; Joundi et al., 2017). Odderson et al. (Odderson et al., 1995) described a similar approach.

2.1.3.2 Frequency and Time of Screening

The percentage patients who were screened ranged from 12.1 to 100%. Differences were due to screening only participants perceived to be at risk, adherence to local protocols and study design. In 4 (Al-Khaled et al., 2016; Bray et al., 2017; Hinchey et al., 2005; Joundi et al., 2017) out of the 5 stroke registries, the incidence of screening ranged from 61 to 87.7%. All patients underwent a screen in the Bernese Stroke Registry study (Arnold et al., 2016). Hinchey et al.(Hinchey et al., 2005) found adherence to dysphagia screening was higher in hospitals with a formal DSP compared to those without (78 vs. 56%), and formal dysphagia screening was associated with increased adherence to completing the screen before oral intake. Time of screen is shown in Table 2.1.

2.1.3.3 Type and Methods of Specialist Swallow Assessment

Six studies reported patients seen for a clinical swallow assessment or consultation by a SLP (Bray et al., 2017; Hinchey et al., 2005; Joundi et al., 2017; Perry and McLaren, 2000; Casaubon et al., 2015; Odderson et al., 1995) or equivalent trained professional (Al-Khaled et al., 2016). No studies reported use of a validated assessment. There was limited information on what comprised a specialist swallow assessment (online suppl. Appendices). Two studies (Palli et al., 2017; Odderson and McKenna, 1993) used the terms SLP “screening” and “assessment” interchangeably but did not provide information on what each involved. Odderson et al. (Odderson et al., 1995) reported that where a patient did not meet the criteria for safe swallowing, swallowing evaluation was completed by an SLP and reviewed daily. Al-Khaled et al. (Al-Khaled et al., 2016) reported that if swallowing difficulties were suspected following the screen, further dysphagia tests were performed.

Table 2.1 Study characteristics

Study	Design, Setting, Country	Stroke Type	Participants	Time of screen
Al-Khaled et al. (2016)	Prospective observational, Germany	Ischaemic stroke	12,276, M age 73 ± 13, median NIHSS 4 (IQR 2-9). 25.1% dysphagic	55, 39, 4.7 and 1.5% screened within 3, 3 to <24, 24 to ≤ 72, and >72h from admission
Arnold et al. (2016)	Prospective observational, Switzerland	Ischaemic stroke	570, M age 65.1 (range, 19.6-94.7), mean NIHSS dysphagia 9.8 ± 7.0 vs. 4.5 ±5.1 non-dysphagia	< 24h from admission.
Bray et al. (2016)	Prospective observational, UK	Ischaemic and haemorrhagic stroke	63,650, median age 77 (67-85), Mdn NIHSS 4 (IQR 2-9), 38.6% dysphagic	Median time < 2.9h from admission (IQR 1.3-5.7 h)
Hinchley et al. (2005)	Prospective observational, USA	Ischaemic stroke	2, 532, Ave. age (SD) 70.5 (14), mean NIHSS 7.2 (CI 6.8-7.5) ‡	Pre oral intake in 61% (95% CI, 50-72); range at individual sites 22-100%
Hoffmeister et al. (2013)	Retrospective observational, Chile	Ischaemic stroke	677, mean women age 69.8 (95% CI 68-71.6), 66.3 men years (95% CI 68.0-71.6) †‡	< 48h admission
Joundi et al. (2017)	Prospective observational, Canada	Ischaemic stroke	6, 677, Age 80+ years 34.0% not screened vs. 41% screened, mean NIHSS 4.29 not screened vs. 7.9 screened, 47.8% dysphagic *	80.8% ≤ 72h from admission
Maeshima et al. (2014)	Prospective observational, Japan	Ischaemic stroke	292, mean age (SD) 69.9 ± 12.2, 71.6% dysphagic †	1.7 ± 1.7 days from stroke onset
Odderson et al. (1995)	Prospective observational, USA	Ischaemic stroke	124, age of dysphagic 75.2 ±1.5 vs. 75.3 ± 1.4 non-dysphagic. 38.7% dysphagic *†	< 24h of admission
Odderson and McKenna (1993)	Prospective observational, USA	Ischaemic stroke	121, average age 73.9 †‡	< 24h of admission
Palli et al. (2017)	Quasi experimental, Austria	Ischaemic stroke	384, mean age 72.3±13.7, mean NIHSS 3, 37.5% dysphagic	Median 7h (range, 1-69) (intervention group)
Perry and McLaren (2000)	Quasi experimental design, UK	Acute stroke	400, mean age (SD) Pre-test 73.4 (12.6)/71.6 (13.3) Post-test, median NIHSS Pre-test 7 (IQR 5-12)/Post-test 8 (IQR 4-13), % dysphagia 43.1% post-test vs. 41.6% pre test	< 24h from admission. 74.5% screened ≤ 24h in post-test vs. 57.3% pre test, p<0.001
Smithard et al. (1996)	Prospective observational, UK	Acute stroke	121, median age 79 (range, 40-93), 50% dysphagic †	Days 0-3, 7

* Mean/ median age not available, † NIHSS not available, ‡ % dysphagia not available

2.1.3.4 Frequency and Time of Assessment

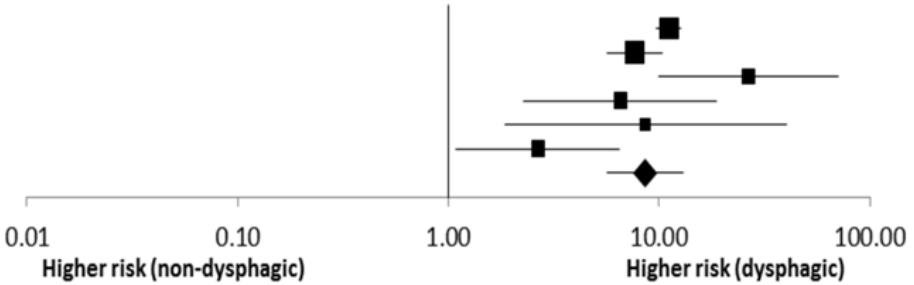
The proportion of patients who had an SLP assessment varied between studies. Bray et al. (Bray et al., 2017) found 39% of all patients had an SLP assessment contrasting with Odderson and McKenna (Odderson and McKenna, 1993) 87% assessed and subsequently treated (61%). Hinchey et al. (Hinchey et al., 2005) stated 22% received an SLP bedside or formal examination. Joundi et al. (Joundi et al., 2017) reported 77% of patients who had a documented screen were assessed by SLP. Four studies provided information on when patients were seen by an SLP (Bray et al., 2017; Palli et al., 2017; Perry and McLaren, 2000; Odderson and McKenna, 1993). Bray et al. (Bray et al., 2017) reported 39% had an SLP assessment 22.9 h post admission (median; IQR 6.2–49.4h). Perry and McLaren (Perry and McLaren, 2000) reported that, in the post-test study group, 56% were assessed within 72 h compared to 39% in the pre-test group ($p < 0.058$). Odderson and McKenna (Odderson and McKenna, 1993) reported an SLP assessment on Day 2. On Day 5, a decision was made about the need for alternative nutritional support, for example, percutaneous gastronomy tube (PEG). Palli (Palli et al., 2017) reported that prior to the implementation of 24/7 nurse screening, patients had a swallow assessment 20 hours from admission (range 1–183 h).

Three studies referred to instrumental investigations or contrast radiography (Arnold et al., 2016; Smithard et al., 1996; Maeshima et al., 2014); Smithard et al. (Smithard et al., 1996) performed VFS when possible within 24 h of the bedside assessment, and further dysphagia evaluation was performed by VFS or FEES as part of the GUSS if a patient scored < 5 points. No information was provided on number of patients for these investigations. Maeshima et al. (Maeshima et al., 2014) reported contrast radiography was performed if any abnormality in bedside swallow assessment or pulmonary aspiration with oral intake was suspected but did not provide information on how often this occurred.

Fig. 2.2 OR of SAP in dysphagia versus non-dysphagia patients.

Study	Dysphagia patients: with SAP	Dysphagia patients: Total	Non-dysphagia patients: with SAP	Non-dysphagia patients: Total	Odds Ratio (95% CI)		Random effects weights
Al-Khaled et al. 2016	917	2166	337	8856	11.13	(9.74, 12.71)	31.2%
Ioundi et al. 2017	322	2135	52	2635	7.64	(5.67, 10.3)	27.7%
Arnold et al. 2016	27	91	5	447	26.53	(9.95, 70.71)	11.6%
Maeshima et al. 2014	52	157	4	79	6.54	(2.28, 18.74)	10.5%
Perry and McLaren 2000	11	62	2	97	8.60	(1.84, 40.14)	6.0%
Smithard at al. 1996	20	40	9	48	2.67	(1.09, 6.5)	13.0%
Total					**8.57**	**(5.65, 13)**	**100.00%**

Random effects model: I^2 = 36.9% ; Q = 7.93 df =5 (P = 0.160); Overall effect Z = 10.1 (P<0.001)



2.1.3.5 Type and Methods of Dysphagia Management

Nine studies (Al-Khaled et al., 2016; Arnold et al., 2016; Hinchey et al., 2005; Joundi et al., 2017; Perry and McLaren, 2000; Smithard et al., 1996; Odderson et al., 1995; Odderson and McKenna, 1993; Maeshima et al., 2014) referred to types and methods of dysphagia management during the acute stroke phase. The level of detail was limited. Types of management included direct, indirect and compensatory strategies. Examples of direct strategies were NBM with enteral or parenteral feeding/fluids (Al-Khaled et al., 2016; Arnold et al., 2016; Hinchey et al., 2005; Joundi et al., 2017; Perry and McLaren, 2000; Smithard et al., 1996; Odderson et al., 1995; Odderson and McKenna, 1993; Maeshima et al., 2014), if the swallow was unsafe, or if supplementary nutrition/hydration of oral intake was insufficient, therapeutic eating of small amounts, diet modification, and adjusted posture (Hinchey et al., 2005; Perry and McLaren, 2000; Odderson et al., 1995; Maeshima et al., 2014). Indirect strategies included oral care, oral articulation exercises, and pharynx cooling stimulation (Maeshima et al., 2014). Compensatory strategies included chin tuck, head rotation, and multiple swallowing (Maeshima et al., 2014). Al-Khaled et al. (Al-Khaled et al., 2016) referred to SLP initiating measures of therapy but did not describe what this involved.

2.1.3.6 Definition and Diagnosis of Pneumonia

The Centers for Disease Control and Prevention (CDC) criteria (Horan et al., 2008) were used to define pneumonia in 3 out of 12 studies (online suppl. Appendices) (Arnold et al., 2016; Hinchey et al., 2005; Maeshima et al., 2014). One study (Palli et al., 2017) used the PISCES SAP diagnostic criteria (Smith et al., 2015). Four used a combination of clinical symptoms, signs and radiologic findings on X-ray and laboratory results (Arnold et al., 2016; Joundi et al., 2017; Perry and McLaren, 2000; Smithard et al., 1996). The definition for 4 studies was based on clinician initiation of antibiotics (Bray et al., 2017; Perry and McLaren, 2000; Hoffmeister et al., 2013; Smithard et al., 1996). Odderson et al. (Odderson et al., 1995) referred to criteria for

aspiration pneumonia but did not define the criteria. Odderson and McKenna (Odderson and McKenna, 1993) provided no definition.

Information on measurement of when pneumonia was reported varied. Most studies reported pneumonia during hospitalization (Al-Khaled et al., 2016; Arnold et al., 2016; Hinchey et al., 2005; Palli et al., 2017; Perry and McLaren, 2000; Hoffmeister et al., 2013; Odderson et al., 1995; Odderson and McKenna, 1993). Two studies reported within 7 days of admission (Bray et al., 2017; Smithard et al., 1996). Maeshima et al. (Maeshima et al., 2014) reported pneumonia pre/post 72h of admission and one study reported within 30 days of hospitalisation (Joundi et al., 2017).

2.1.3.7 Incidence of SAP

Overall incidence was reported in 8 studies (Al-Khaled et al., 2016; Arnold et al., 2016; Bray et al., 2017; Hinchey et al., 2005; Hoffmeister et al., 2013; Odderson et al., 1995; Odderson and McKenna, 1993; Maeshima et al., 2014) (online suppl. Appendices) and ranged from 0 to 23.6% (Odderson et al., 1995; Hoffmeister et al., 2013), with the largest population at 8.7% (Bray et al., 2017). Maeshima et al. (Maeshima et al., 2014) found 26.9% developed SAP had early onset pneumonia with development of pneumonia within 72 h of admission. Six studies compared rates of pneumonia between dysphagia and non-dysphagia patients (Al-Khaled et al., 2016; Arnold et al., 2016; Joundi et al., 2017; Perry and McLaren, 2000; Smithard et al., 1996; Maeshima et al., 2014). Patients with dysphagia were at increased risk of SAP compared to patients without dysphagia (OR 8.57; 95% CI 5.65–13; Fig. 2.2). Five studies found that implementing a formal DSP or clinical pathway significantly reduced pneumonia rates (Hinchey et al., 2005; Palli et al., 2017; Perry and McLaren, 2000; Odderson et al., 1995; Odderson and McKenna, 1993). Odderson and McKenna (Odderson and McKenna, 1993) found implementing a clinical pathway which involved an integrated team with immediate rehabilitation improved rates of pneumonia.

2.1.3.8 Associations between SAP and Dysphagia Screening

Six studies analysed associations between dysphagia screening and SAP (Al-Khaled et al., 2016; Bray et al., 2017; Hinchey et al., 2005; Joundi et al., 2017; Hoffmeister et al., 2013; Maeshima et al., 2014). Hinchey et al. (Hinchey et al., 2005) found that the pneumonia rate was significantly higher in those who had any screen versus those who did not ($p < 0.0001$). Joundi et al. (Joundi et al., 2017) found patients who failed dysphagia screening were more likely to develop pneumonia (aOR 4.71; 95% CI 3.43–6.47) and aspiration pneumonia (aOR 6.5; 95% CI 4.2–9.9) compared to those that passed. Maeshima et al. (Maeshima et al., 2014) found that an abnormal screen was associated with SAP (OR 2.65; 95% CI 0.90–9.72; $p = 0.0774$). Hoffmeister et al. (Hoffmeister et al., 2013) found no association between dysphagia screening and pneumonia (aOR 1.58 95% CI 0.60–4.15; $p = 0.36$). However, neither of these results was statistically significant (Hoffmeister et al., 2013; Maeshima et al., 2014).

Three studies analysed the effect of early dysphagia screening (EDS) and patients developing pneumonia. Palli et al. (Palli et al., 2017) found that 24/7 dysphagia screening out-side the working hours of SLP significantly reduced time to dysphagia screening from median 20 to 7 h ($p = 0.001$). Two studies found risk of developing SAP was increased with late dysphagia screening (Al-Khaled et al., 2016; Bray et al., 2017). EDS (< 24 h of admission) was independently associated with decreased risk of SAP (OR 0.68; 95% CI 0.52–0.89) (Al-Khaled et al., 2016). Bray et al. (Bray et al., 2017) found a modest association between time from admission and time to dysphagia screen with the longest delays in screening having 36% higher odds of SAP compared to those in the first quartile.

2.1.3.9 Associations between SAP and Specialist Swallow Assessment

Bray et al. (Bray et al., 2017) found a strong independent relationship between delay in SLP assessment and incidence of SAP. Delays in SLP assessment were associated with an absolute increase in the risk of SAP of

3% over the first 24 h. Delays in SLP assessment > 24 h were associated with an additional 4% absolute increase in SAP. Patients in the slowest quartile had 1.98 (1.67–2.35) odds of SAP compared with patients receiving the quickest SLP assessment. Smithard et al. (Smithard et al., 1996) found no evidence to justify the routine use of VFS in screening for aspiration in acute stroke.

2.1.3.10 Associations between SAP and Dysphagia Management

Alternative feeding was the only management strategy where data were analysed in relation to SAP. Arnold et al. (Arnold et al., 2016) found dysphagia tube-fed compared to dysphagia non-tube patients had higher risk for in-hospital pneumonia and need of antibiotic treatment. After adjusting for confounding variables, the association between tube placement and pneumonia was not statistically significant (OR 2.2; 95% CI 0.89–5.5; p = 0.087). Maeshima et al. (Maeshima et al., 2014) found 53.8% of patients who developed SAP were NBM with nasogastric and enteral feeding and developed SAP after 72 h. These patients and those who developed early onset pneumonia had the most severe neurological syndromes and cognitive dysfunctions.

2.1.4 Discussion

A recently published review found insufficient evidence to determine the effect of DSP (Smith et al., 2018). However Smith et al. (2018) included only randomized controlled trials and did not focus specifically on pneumonia as an outcome. Our review found emerging evidence that EDS is associated with lower incidence of SAP and supports current guidelines that all patients should be screened for dysphagia on admission before oral intake. There may be reason for performing later screening in patients with altered consciousness (Al-Khaled et al., 2016). In studies that examined association between dysphagia screening and development of SAP, a range of screening practices was used, thereby precluding the recommendation of a particular protocol. A formal written protocol improved adherence and

demonstrated higher numbers of patients being screened. An integrated team approach and clinical pathway also improved rates of pneumonia.

Delays in SLP assessment were associated with SAP with an absolute risk of pneumonia incidence of 1% per day of delay. There was limited information about the assessment components. One study evaluated the role of VFS to screen for aspiration, one of the main risk factors for SAP. There was no evidence to support its routine use during the first 72 h of admission. Limited use of VFS in the acute phase post stroke is expected, given patients may be too acutely unwell to leave the ward. No study reported the use of FEES, which has the advantage of administration at the bedside, is cost effective and with no radiation exposure can be repeated if clinically indicated. When used selectively, FEES has been shown to reduce pneumonia rates, improve functional outcomes and is therefore receiving increasing support in acute stroke dysphagia assessment (Bax et al., 2014; Leder and Espinosa, 2002). Stroke-related dysphagia may be graded using endoscopic scales such as the Fibre Optic Endoscopic Dysphagia Severity Scale (Warnecke et al., 2009; Warnecke et al., 2017) or Penetration-Aspiration Scale (Colodny, 2002).

The potential for tube feeding to contribute to infection by promoting oral-pharyngeal colonisation or aspiration, and other factors such as poor oral and dental hygiene, requiring assistance with mobility, positioning, and concurrent chest and cardiac disease, have been identified as potential risk factors for SAP (Bevan, 2015; Brogan et al., 2015). Further research about the association between these factors and dysphagia patients developing SAP would improve our understanding of their impact during the first 72 h of admission and potentially improve patient outcomes.

No randomized controlled trials examining a specific DSP or specialist swallow assessments and the impact on SAP was found. The heterogeneity of study designs, reporting methods and the large size of one study (Bray et al., 2017) precluded meta-analysis. Caution is recommended in drawing

overall conclusions and generalising. Future reporting would benefit from a more standardised approach to allow meta-analyses.

2.1.5 Conclusion

This review found increasing evidence that early dysphagia screening and specialist swallow assessment help to reduce the odds of SAP. Variation in assessment methods and management factors (e.g. tube feeding) may be associated with SAP. Further understanding is needed on the effect of these variations and other confounding factors, which may contribute to the development of SAP during this acute phase.

The supplementary material is available in the Appendix C – Supplementary Material for the Systematic Reviews (Page 297).

2.2 Factors Associated with Risk of Stroke-Associated Pneumonia in Patients with Dysphagia: A Systematic Review

Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Smith, C. J. and Pownall, S. (2020) 'Factors Associated with Risk of Stroke-Associated Pneumonia in Patients with Dysphagia: A Systematic Review.' Dysphagia, 35(5), Oct, 2019/09/08, pp. 735-744.

2.2.1 Introduction

Stroke-Associated Pneumonia (SAP) is common post stroke affecting 14% of patients (Kishore et al., 2015), and is associated with increased risk of in hospital mortality (Westendorp et al., 2011), prolonged length of hospital stay (Finlayson et al., 2011), and has considerable economic impact on healthcare resources (Ali et al., 2018). The pathophysiology of SAP is multifactorial. The combination of stroke-induced immuno-deficiency and aspiration of oropharyngeal secretions and gastric contents into the lungs related to impaired consciousness and dysphagia predisposes patients to SAP in the first few days post stroke (Hannawi et al., 2013). Respiratory tract infections may also precede stroke thereby contributing to stroke etiopathogenesis (Emsley and Hopkins, 2008).

Acute stroke impairs the peripheral immune system, which is mediated by over-activation of the sympathetic nervous system and hypothalamic–pituitary–adrenal axis. Inhibition of peripheral cellular immune responses is characterized by transient lymphopenia and monocyte deactivation, which increases susceptibility to infection (Dirnagl et al., 2007). In a murine model of human stroke, stroke mice developed pan-lymphocytopenia and lymphocyte apoptosis in lymphoid tissues, which was reversed by either β-adrenergic receptor blockade or glucocorticoid receptor inhibition (Prass et al., 2003). Alteration of tracheal epithelium caused by stroke immunomodulation has been shown to impair pulmonary clearance (Winek et al., 2018). Reduced pulmonary clearance and impaired mobility related to

decreased airway entry and impaired drainage of secretions from the lungs may contribute to development of pneumonia (Brogan et al., 2014; Winek et al., 2018).

Patients with dysphagia are more than three times at risk of developing pneumonia after stroke and the risk increases 11-fold in patients with confirmed aspiration (Martino et al., 2005). Early dysphagia screening and specialist swallow assessment by a speech and language pathologist (SLP) may reduce the risk of SAP (Eltringham et al., 2018). However, patients who are exclusively fed via the enteral route are also at risk of developing SAP. Tube feeding (Langdon et al., 2009) and poor oral hygiene (Lyons et al., 2018) may increase the risk of pneumonia by promoting bacterial colonization of the oropharynx. The presence of oral and dental disease causes alterations of oropharyngeal flora, and reduced saliva flow increases the bacterial density of the saliva. The presence of a nasogastric tube (NGT) may impact on bacterial colonization due to formation of biofilms on the tube (Langdon et al., 2009), and predispose patients to gastro-esophageal reflux and vomiting (Warusevitane et al., 2015). Aspiration of bacteria laden secretions and infected refluxed material increases the risk of pneumonia. Functional status such as dependence for oral care and feeding has been shown to be significantly associated with respiratory infection (Langmore et al., 1998).

A range of factors may be associated with SAP. These include risk factors associated with patient characteristics such as age, stroke severity, level of consciousness, as well as co morbidities such as chronic obstructive pulmonary disease and coronary artery disease (Benfield and Michou, 2016). However, these risk factors are outside the scope of this review. For this review, factors were defined as medical interventions to manage physiological status and care processes systemic to patients with dysphagia, in acute phase stroke and were identified from references and citation searching from a precursory systematic review (Eltringham et al., 2018).

The role of these pathophysiological processes in contributing to SAP in stroke patients with dysphagia, and the potential for therapeutic interventions to prevent SAP, is not well understood. We therefore undertook a systematic literature review with the aim of identifying care processes and/or interventions that were associated with modified risk of SAP in patients with dysphagia in acute stroke as targets for future clinical trials and evidence for implementation of a care process or intervention.

2.2.2 Methods

2.2.2.1 Search Strategy and Selection Criteria

A systematic review was undertaken according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2009), and Centre for Reviews and Dissemination guidance (CRD, 2009). A building block (Booth, 2008) approach identified search terms for each concept. The concepts were dysphagia (Concept A), stroke (Concept B), risk factors (Concept C) and SAP (Concept D). These were combined using the Boolean AND operator. Two search strategies were used to develop the search terms: National Clinical Guideline for Stroke (ISWP, 2016b) and the Pneumonia in Stroke Consensus (PISCES) Group (Smith et al., 2015). Co-authors (SP, KS, MG) reviewed the search strategy (Electronic Supplementary Material). Electronic databases were searched from inception to 14/2/2017 for relevant studies: CINAHL (via EBSCOhost), COCHRANE (via Wiley Online), EMBASE (via NICE Healthcare Data bases), MEDLINE (via EBSCOhost) and SCOPUS. In addition, references and citations of included studies were screened. An example of the search strategy for the MEDLINE search is included in the Supplementary Material (Table1).

The review was restricted to peer-reviewed English language stroke research. Studies of dysphagia only patients, studies comparing dysphagia and non-dysphagia patients and unselected patients that reported dysphagia and evaluated factors associated with a recorded frequency of SAP were

included. Acute phase stroke is typically defined as ≤ 72 h from admission. The time restriction of ≤ 72 h might not be explicit in the title/abstract; therefore, if the abstract met all the other inclusion criteria, it was included in the next stage of the screening process. Non-stroke or mixed population studies, those of exclusively intubated and mechanically ventilated patients, and studies not documenting SAP or pneumonia post stroke or pre-existing pneumonia were excluded.

Medical interventions included NGT feeding, oral care and prophylactic measures, for example, screening for immunodepression, antibiotics, management of gastroesophageal reflux and the use of angiotensin-converting enzyme (ACE) inhibitors which have been suggested to reduce risk of pneumonia (Caldeira et al., 2012; Bevan, 2015). Care processes included positioning, mobilization and staff competences and adherence to safe swallowing techniques. The primary outcome of interest was SAP. SAP is defined as the spectrum of lower respiratory tract infections within the first 7 days after stroke onset (Smith et al., 2015). However, given the variation in reporting of post-stroke pneumonia and difficulty establishing stroke onset in some patients, for the purpose of this review studies were included that reported pneumonia within hospitalization and ≤ 30 days of stroke onset.

Two authors independently applied the inclusion/exclusion criteria to titles and abstracts for eligibility (Supplementary Material Table 2). Differences were forwarded to a third author for consensus. Abstracts that met the inclusion criteria were recommended for full-text reading and assessed by SAE. Corresponding authors were contacted to resolve eligibility and/or data extraction issues.

2.2.2.2 Data Abstraction and Analysis

SAE designed and piloted a data extraction form based on Royal College of Physicians National Clinical Guideline for Stroke (ISWP, 2016a) and independently extracted data for the titles. Data extraction included study design, baseline characteristics of the population, factors and association

with SAP (Supplementary Material Tables 3–4). Authors were contacted if data were not available. The extracted results were synthesized into the defined groups and organized thematically based on the National Clinical Guideline for Acute stroke care (ISWP, 2016b).

2.2.2.3 Risk of Bias

Randomized control trials (RCTs) were assessed for risk of bias and quality (Higgins et al., 2011). Risk of bias tables were used to describe the methods used in each study and whether the results were at risk (Supplementary Material Table 5). Non-RCTs were assessed using the Critical Appraisal Skills Programme (CASP) checklists (CASP, 2017).

2.2.2.4 Statistical Analysis

Inter-rater reliability for the inclusion/exclusion criteria was analysed using the Kappa statistic. The percentage of variation across studies due to heterogeneity was evaluated using I squared (I^2) (Higgins et al., 2003). Review Manager 5.3 (The Cochrane Collaboration, 2014) and Microsoft Excel produced forest plots for illustration only (Neyeloff et al., 2012).

2.2.3 Results

Database searching found 1326 references and 12 arose through other sources (Fig. 2.3). Inter-rater reliability for the inclusion/exclusion criteria was 0.78. Thirty-one full- text articles were assessed for eligibility. Eleven studies of 10 ischemic and hemorrhagic stroke patient cohorts were included (Table 2.2). Kalra et al. (Kalra et al., 2016) and Kalra et al. (Kalra et al., 2015) used the same RCT data. Study designs included RCTs (30%) (Kalra et al., 2016; Kalra et al., 2015; Gosney et al., 2006; Warusevitane et al., 2015), prospective (20%) (Langdon et al., 2009; Hoffmann et al., 2017) and retrospective (40%) (Arai et al., 2017; Brogan et al., 2015; Gandolfi et al., 2014; Schwarz et al., 2018) observational studies and one quasi-experimental design (Aoki et al., 2016). Europe hosted 55% of studies,

(Kalra et al., 2016; Warusevitane et al., 2015; Kalra et al., 2015; Gosney et al., 2006; Hoffmann et al., 2017; Gandolfi et al., 2014), Australia 27% (Langdon et al., 2009; Brogan et al., 2015; Schwarz et al., 2018) and Japan 18% (Arai et al., 2017; Aoki et al., 2016). Five studies included dysphagia only populations (Warusevitane et al., 2015; Gosney et al., 2006; Kalra et al., 2016; Kalra et al., 2015; Arai et al., 2017; Gandolfi et al., 2014), 2 studies included patients with and without dysphagia (Gosney et al., 2006; Hoffmann et al., 2017), and 4 were unselected (Langdon et al., 2009; Brogan et al., 2015; Schwarz et al., 2018; Aoki et al., 2016). There was variation in the way participant characteristics such as National Institutes of Health Stroke Scale (NIHSS) and age were reported and missing information. Based on available data, the overall mean NIHSS score was 12 (Warusevitane et al., 2015; Kalra et al., 2016; Kalra et al., 2015; Hoffmann et al., 2017; Gandolfi et al., 2014; Aoki et al., 2016) and mean age of participants was 76 years (Warusevitane et al., 2015; Kalra et al., 2016; Kalra et al., 2015; Hoffmann et al., 2017; Arai et al., 2017; Gandolfi et al., 2014; Schwarz et al., 2018).

Figure 2.3: Search methodology and outcome

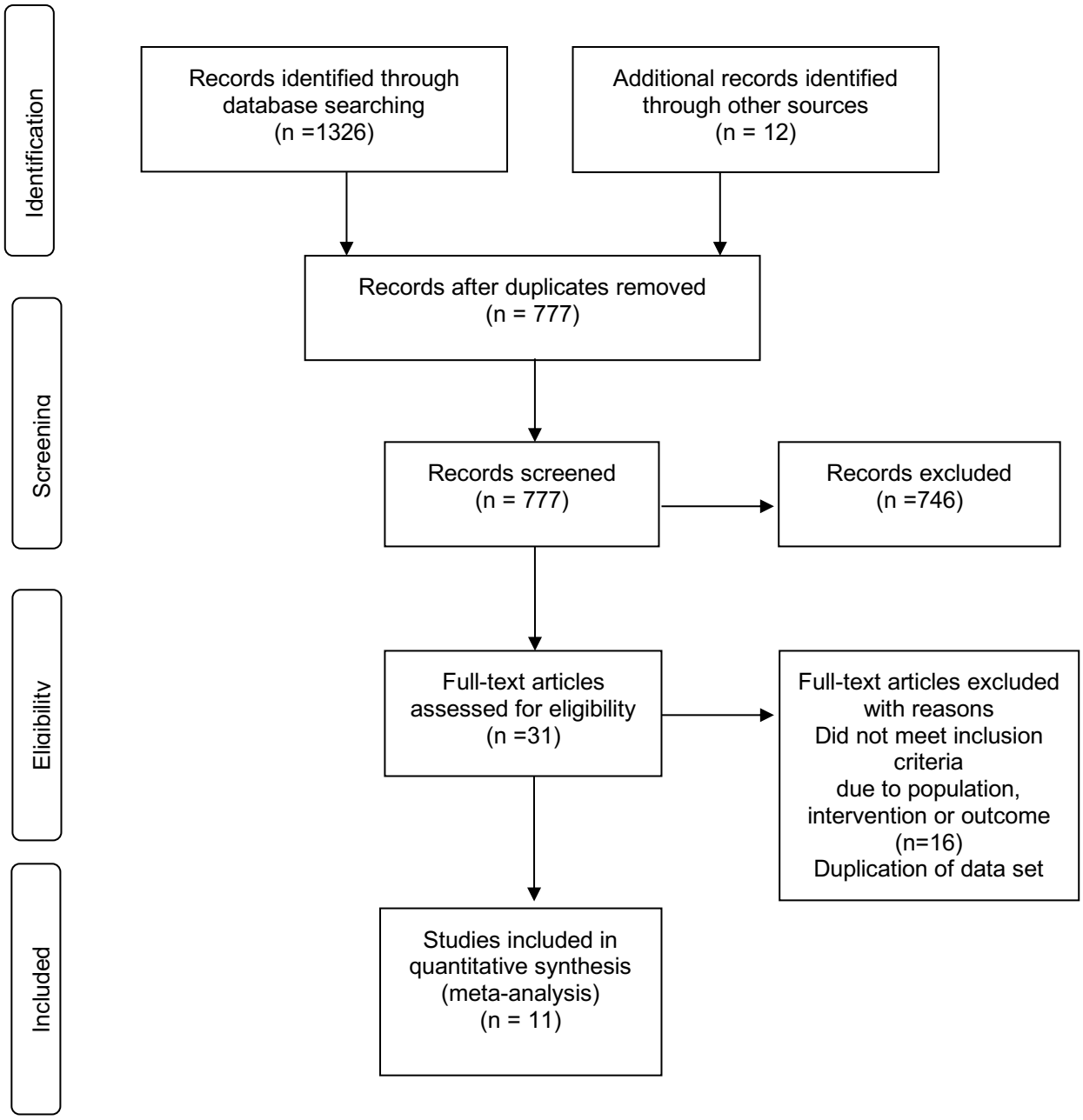


Table 2.2: Study characteristics

Author, year, county	Study design	Stroke Type	Participants	Intervention	Association with SAP
Aoki et al. (2016), Japan	Quasi-experimental	Ischemic and hemorrhagic	132 pre/173 post unselected; Age pre 70.0±12.2 vs. post 70.1±11.5 (p 0.91). Mdn NIHSS pre 5 (IQR 2-13) vs. 5 (IQR 2-14) post	MDT swallowing approach	aHR 0.41, 95% CI 0.19-0.84, p=0.02
Arai et al. (2017), Japan	Retrospective observational	Ischemic and intracerebral hemorrhage	335 dysphagia only; Mdn age 82 yrs. (IQR, 74-88 yrs.) Mdn NIHSS 15 (11-24)	Histamine H2-Blocker or PPI or none	RR of H2B 1.24, 95% CI; 0.85-1.81 and 2.00 in PPI, 95% CI;1.12-3.57
Brogan et al. (2015), Australia	Retrospective observational	Unreported	533 unselected; Age >80 yrs. 33.4%	NGT	OR 3.91;95% CI 1.73-8.80; p=0001
Gandolfi et al. (2014), Italy	Retrospective observational	Ischemic and hemorrhage	84 dysphagia only; 39 T+ vs. 45 T-. M (± SD) age 77.9 (8.55). NIHSS 13.88 (7.12)	MDT swallowing approach	aOR 0.34,95% CI 0.07-1.49
Gosney et al. (2006), UK	RCT double blind PBO	Unreported	203 (58 w/dysphagia); Mdn age: active 78 yrs. vs. placebo 62 yrs. (H1), active 68 yrs. vs. PBO 74 yrs. (H2), active 71 yrs. vs. PBO 74 yrs. (H3)	SDD oral gel	7/8 dysphagia patients developed pneumonia (N=1 active vs. 6 placebo).
Hoffman et al. (2016), Germany	Prospective observational	Ischemic	484 (111 w/ dysphagia); M age 69.9 (11.8). Mdn (IQR) NIHSS 4 (2-7)	Screening for SAP, dysphagia and biomarkers	Dysphagia and decreased monocytic HLA-DR predictors of SAP
Kalra et al. (2015), UK	Prospective, multicenter, cluster RCT	Ischemic and hemorrhagic	1088 dysphagia only; M age (SD) 77.8 (12.0), Mdn NIHSS 15 (IQR 9-20)	Prophylactic Antibiotics	Algorithm SAP; aOR 1.21; 95% CI 0.71-2.08, p=0.489.
Kalra et al. (2016), UK	Prospective, multicenter, cluster RCT	Ischemic and hemorrhagic	1088 dysphagia only ; M age (SD) 77.8 (12.0), Mdn NIHSS 15 (IQR 9-20)	NGT	Algorithm SAP; aOR 1.26, 95% CI 0.78-2.03, p=0.353
Langdon et al. (2009), Australia	Prospective observational	Ischemic	330 unselected; M age SAP (SD) 71.7± 13.0	NGT	aRR 2.76 (95% CI 1.26-6.01), p=0.011
Schwarz et al. (2017), Australia	Retrospective cohort	Ischemic	110 unselected, Ave age 69.87, range 28-94	NGT	RR 12.609 (CI 95% OR 21.54), p<0.0001
Warusevitaine et al. (2014), UK	Phase II RCT double-blind PBO	Ischemic and hemorrhagic	60 dysphagia only, M age 78. M NIHSS 19.25	Metoclopramide	aRR 5.24 (95% CI; 2.43-11.27), p value <0.001).

2.2.3.1 Assessment of Quality And Bias

Study quality ranged from high-quality RCTs to moderate quality quasi-experimental studies to lower quality retrospective observational studies (Supplementary Material Table 4). Overall, the RCTs were deemed to have a low risk of bias. Potential sources of selection bias in the cluster RCT studies (Kalra et al., 2016; Kalra et al., 2015) included where patients at increased risk of SAP might have been preferentially recruited into the intervention group. A limitation of the Kalra et al. (Kalra et al., 2016) study was that data were derived from an RCT and a prospective cohort data structure was assumed, which may have resulted in selection bias. A possible source of performance bias was participants and researchers being aware of allocation treatment. The open intervention allocation could potentially influence physician diagnosis of pneumonia.

Other possible sources of bias and quality considerations in the RCT and non-RCT studies include small population size and risk of measurement bias. There was a lack of objective measurement of the MDT swallowing approach (Aoki et al., 2016) and the potential bias of progressive proficiency of implementing the MDT protocol over time (Gandolfi et al., 2014). Other examples of measurement bias included lack of information about the diagnosis and method of assessment of dysphagia and subsequent measurement and severity rating, and classification of stroke severity.

2.2.3.2 Diagnosis and Frequency of SAP

Overall incidence was reported in 10 studies (Langdon et al., 2009; Warusevitane et al., 2015; Kalra et al., 2016; Kalra et al., 2015; Gosney et al., 2006; Hoffmann et al., 2017; Arai et al., 2017; Brogan et al., 2015; Schwarz et al., 2018; Aoki et al., 2016) (Supplementary Material Table 5, Fig. 1) and ranged from 3.9 to 56.7% (Warusevitane et al., 2015; Gosney et al., 2006), with the largest dataset at 11.3% (Kalra et al., 2016; Kalra et al., 2015). The Centers for Disease Control and Prevention (CDC) criteria (Horan et al., 2008) were used to define pneumonia in the majority of

studies. One study made a diagnosis based on the British Thoracic Society recommendations (Warusevitane et al., 2015). The STROKE-INF trial data set used blinded application of CDC criteria and physician-diagnosed pneumonia (Kalra et al., 2015; Kalra et al., 2016). Four used a combination of clinical symptoms, radiologic findings on X-ray and laboratory results and combined antibiotics (Langdon et al., 2009; Warusevitane et al., 2015; Gosney et al., 2006; Gandolfi et al., 2014). Two studies provided no definition (Brogan et al., 2015; Schwarz et al., 2018).

Measurement of pneumonia timing varied. Four studies reported pneumonia during hospitalization (Gosney et al., 2006; Hoffmann et al., 2017; Gandolfi et al., 2014; Aoki et al., 2016). Three studies reported within 14 days of admission (Kalra et al., 2016; Arai et al., 2017) and one from 7 days of admission (Brogan et al., 2015). Warusevitaine et al. (Warusevitane et al., 2015) and Langdon et al. (Langdon et al., 2009) reported at 21 days and 30 days, respectively. Schwarz et al. (Schwarz et al., 2018) did not report the period of diagnosis. Marked variation in study design and reporting of participant characteristics prohibited meta-analysis.

2.2.3.3 Medical interventions

2.2.3.3.1 Prophylactic Measures

Screening for Stroke-Induced Immunodepression

One study (Hoffmann et al., 2017) investigated the predictive properties of biomarkers of immunodepression (mHLA-DR expression), as well as inflammation (IL-6), and infection (LBP) during the acute phase of stroke, and incidence of SAP stratified for patients with and without dysphagia.

Incidence and risk of SAP

Incidence of SAP in patients with dysphagia was 16.2% vs. 5.2% overall. When combining all three biomarkers and presence of dysphagia, only mHLA-DR [OR 0.29 (95% CI 0.09–0.94; p = 0.0398)] and dysphagia [OR

5.74 (95% CI 2.21–14.89; p = 0.0003)] were independent predictors of SAP. Patients with dysphagia and low mHLA-DR expression were at particularly high risk of SAP (18.8%). In patients without dysphagia and who had normal mHLA-DR expression, no SAP was observed (0%).

Medication Use

Four studies investigated use of pharmacological agents for reducing pneumonia: prophylactic antibiotics (Kalra et al., 2015), acid suppressive medications (Arai et al., 2017), metoclopramide—an antiemetic and prokinetic drug (Warusevitane et al., 2015), and selective decontamination of the digestive tract (SDD) (Gosney et al., 2006). No studies assessed ACE inhibitors and their association with SAP in patients with dysphagia. Three studies were RCTs (Warusevitane et al., 2015; Kalra et al., 2015; Gosney et al., 2006). Preventative antibiotics were administered in Nil by mouth (NBM) patients ≤48 h post onset of stroke symptoms (Kalra et al., 2015). In a second study, patients who were unable to eat orally for 14 days or more after admission were exposed to acid suppressive drugs: famotidine, a Histamine H2-Blocker (H2B), and omeprazole, a Proton Pump Inhibitor (PPI) (Arai et al., 2017). The choice of drugs was at the discretion of the treating physician. Warusevitaine et al. (Warusevitane et al., 2015) study participants received metoclopramide or placebo 3× daily via the NGT for 21 days or until NGT feeds were discontinued. SDD involved oral gel containing antimicrobial drugs, applied topically to the mouth four times daily. Patients were randomized to receive either the SDD gel or placebo. Treatment was continued for 3 weeks for patients with dysphagia and for 2 weeks for those with a normal swallow.

Incidence and risk of SAP

Kalra et al. (Kalra et al., 2015) found that prophylactic antibiotics did not affect the incidence of algorithm-defined post-stroke pneumonia in the antibiotic group (13%) versus the control group (10%) (aOR 1.21; 95% CI 0.71–2.08, p = 0.489). Additionally, no differences were noted in physician-diagnosed post-stroke pneumonia between dysphagic patients in the

antibiotic group (16%) versus the control group (15%) (aOR 1.01; 95% CI 0.61–1.68, $p = 0.957$).

Arai et al. (Arai et al., 2017) found that the daily incidence of pneumonia in the PPI group (6.38%, 95% CI 3.78–10.1) was 1.7 times higher than in the exposed H2B group (3.77%, 95% CI 2.92–4.78). PPI use in patients with dysphagia was associated with increased risk of pneumonia (RR 2.00, 95% CI 1.12–3.57), while use of H2B was not (RR 1.24, 95% CI 0.85–1.81).

Warusevitane et al. (Warusevitane et al., 2015) found there were significantly more episodes of pneumonia in the placebo group (RR 5.24, 95% CI 2.43–11.27; $p < 0.001$) than the metoclopramide group: placebo group mean 1.33 (SD 0.76) vs. metoclopramide group mean 0.27 (SD 0.45).

In Gosney et al. (Gosney et al., 2006), 3.94% ($N = 8$) patients developed pneumonia. Seven of the 8 cases of pneumonia occurred in patients with dysphagia. Patients with dysphagia were twice as likely to have AGNB (aerobic Gram-negative bacteria) organisms, which are implicated in aspiration pneumonia, present in their first swab (< 24 h of admission) than those with a normal swallow, although this did not reach significance. Only 1 dysphagic patient treated with SDD developed pneumonia compared to 6 dysphagic patients in the placebo group. The study did not provide data on how many dysphagic patients with AGNB developed pneumonia compared to those with dysphagia without AGNB.

2.2.3.3.2 Nasogastric Tubes (NGTs)

Four studies (Langdon et al., 2009; Kalra et al., 2016; Brogan et al., 2015; Schwarz et al., 2018) investigated association between NGTs and SAP in acute stroke patients. The characteristics of these studies varied between unselected patients that included patients with dysphagia (Langdon et al., 2009; Brogan et al., 2015; Schwarz et al., 2018) and dysphagia only patients (Kalra et al., 2016). Kalra et al. (Kalra et al., 2016) used the STROKE-INF data set where patients had been randomly assigned to be given either

prophylactic antibiotics or standard stroke unit care. Three studies provided experimental and control data (Langdon et al., 2009; Brogan et al., 2015).

Incidence and risk of SAP

Overall incidence of SAP varied between and within studies. Brogan et al. (Brogan et al., 2015) (37%) and Langdon et al. (Langdon et al., 2009) (41%) reported higher incidence of SAP compared to Kalra et al. who reported rates of incidence for physician-diagnosed (18.5% vs. 15.3%, $p = 0.21$) and algorithm-defined SAP in NGT-fed and No-NGT patients (14.4% vs. 10.1%, $p = 0.046$). The higher rate of algorithm SAP in patients with NGT did not remain significant after adjustment for age, stroke type, severity and chronic lung disease (aOR 1.26; 95% CI 0.78–2.03, $p = 0.35$). Patients with NGT had more severe strokes with impaired consciousness. Preventive antibiotics did not reduce incidence of SAP in patients with NGT [aOR 1.05 (95% CI 0.73–1.52); $p = 0.803$]. Schwartz et al. (Schwarz et al., 2018) did not report incidence of SAP in patients with NGT and did not respond to information requests by the author. Differences in SAP incidence between studies can be partly explained by the different study populations and the lack of adjustment for stroke severity and baseline characteristics (Langdon et al., 2009; Brogan et al., 2015).

There was a high degree of heterogeneity between the three studies ($I^2 = 94\%$) (Langdon et al., 2009; Kalra et al., 2016; Brogan et al., 2015) that provided experimental (NGT) vs. control (No NGT) data. The incompatibility of study designs precluded presenting the data as a meta-analysis. Based on the individual studies, Kalra et al. found no evidence that NGT increased SAP (aOR 1.26; 95% CI 0.78–2.03, $p = 0.35$). In contrast, Brogan et al. found having an NGT (OR 3.91; 95% CI 1.73–8.80; $p = 0001$) and being NBM (OR 5.62; 95% CI 1.54–20.46; $p = 0.0089$) were independently associated with respiratory infections. Langdon et al. also found being enteral fed during admission was a significant risk factor for respiratory infection (aRR 2.76; 95% CI 1.26–6.01, p value 0.011). Schwarz et al. found the presence of an NGT significantly increased the risk of developing

aspiration pneumonia ($p < 0.0001$) with a relative risk of 12.609 (95% CI, OR 21.54).

2.2.3.4 Care Processes

2.2.3.4.1 Multidisciplinary Team Approach (MDT) To Swallowing

Two studies described the implementation of a MDT approach to dysphagia, in dysphagia only (Gandolfi et al., 2014) and unselected patients (Aoki et al., 2016). Aoki et al. MDT participatory team comprised of 9 professionals including doctors, dentists, nurses, physiotherapists (PT), occupational therapists (OT), SLPs, managerial dieticians, dental hygienists and pharmacists. The approach was the cooperation of the various professionals that have the skills to improve the quality of medical care, utilizing the specialist knowledge and skills of each professional. To understand the difference of the MDT approach, frequencies of professional oral care and swallowing evaluations before team organization ('prior period') and the period after team organization ('post period') were evaluated.

In Gandolfi et al. (Gandolfi et al., 2014), a standardized diagnostic and rehabilitative protocol for stroke related dysphagia management was progressively introduced. A MDT of neurologists, nurses, rehabilitation physicians, PTs, nutritionist, SLPs, radiologists and ear nose throat specialists were involved in the implementation. The protocol consisted of 2 phases: a diagnostic phase, aiming to define the swallowing problem and selecting those patients who were eligible for the following rehabilitative phase. The diagnostic phase included clinical and instrumental evaluation by fiberoptic endoscopic evaluation (FEES) and/or videofluoroscopy (VFSS). Rehabilitative treatment for dysphagia proceeded in 3 consecutive phases: Phase 1 sensory stimulation of the oral cavity, oro-facial and breathing exercises, Phase 2 swallowing trials of crushed iced and jellied water and teaching airway protection strategies and Phase 3 weaning from nutritional support by administration of small semisolid meals fractionated throughout the day. During hospitalization the patients received 1-hour individual

sessions of rehabilitation for dysphagia. Pneumonia rates were compared after pre implementation of the protocol for dysphagia (T− group) versus after the implementation of the MDT protocol (T+ group).

Incidence and Risk of SAP

Aoki et al. found pneumonia onset was less frequent in the post group compared to the prior group (6.9% vs. 15.9%; *p*=0.01) and a MDT swallowing approach was related to reduced occurrence of pneumonia onset independent of NIHSS score on admission (aHR 0.41, 95% CI 0.19–0.84, *p*=0.02). The percentage of patients receiving professional oral care (51.7% vs. 12.9%, $p < 0.0001$) and instrumental swallowing evaluations (26.0% vs. 12.1%, $p = 0.002$) were significantly increased in the post group. Gandolfi et al. reported no significant differences between the two groups in the frequency of pneumonia but did not provide incidence data. There was very weak evidence of a reduction in pneumonia risk for the T+ group [aOR 0.34 (0.07–1.49)] compared to the T− group.

2.2.3.4.2 Mobility

Two studies, both of unselected patients investigated reduced mobility and the impact on SAP (Langdon et al., 2009; Brogan et al., 2015).

Incidence and Risk of SAP

Both studies found patients who required full assistance with mobility or had impaired mobility on admission were at significant risk of SAP. Brogan et al. (Brogan et al., 2015) found odds of infection were 6.48 times (95% CI 1.35–31.16; *p*=0.0198) for patients who required full assistance with mobility than those who were able to mobilize. Langdon et al. found impaired mobility on admission was a significant risk factor for respiratory infection (aRR 2.86; 95% CI 1.26–6.48, *p* value 0.012) (Langdon et al., 2009).

2.2.3.4.3 Other Care Processes

No studies were retrieved from the search strategy relating to positioning or adherence with recommendations from the dysphagia screen or specialist swallow assessment.

2.2.4 Discussion

We have identified a range of medical interventions and care processes, which may impact on the development of SAP in patients with dysphagia. However, there are insufficient data to recommend any of these at present and interpretation is limited by heterogeneity of studies and reporting. This review has identified a need for further research of candidate processes and interventions.

There is emerging evidence for the use of preventative measures such as screening for stroke-induced immuno-suppression and considering instrumental swallow assessment in patients with low mHLA-DR expressions who have been identified with dysphagia. Further RCTs with larger sample sizes are needed to test this hypothesis and screening for AGNB organisms. Studies need to evaluate the utility and external validity of these medical interventions specifically in relation to optimal timing, point-of- care technology, and what they add to existing dysphagia assessment methods. Further research is also required to evaluate what the intervention might be, for example boosting the immune system in the acute phase, or treating with SDD gel for the duration of the patients' dysphagia.

The findings of Kalra et al. (Kalra et al., 2015) are consistent with a recent Cochrane Review (Vermeij et al., 2018) which found high-quality evidence that antibiotic prophylaxis in people with acute stroke does not reduce post-stroke pneumonia (RR 0.95, 95% CI 0.80–1.13). The PRECIOUS (PREvention of Complications to Improve OUtcome in elderly patients with acute Stroke) Trial is assessing if metoclopramide prevents aspiration (van der Worp, 2017). This has the potential to inform whether the use of

metoclopramide can reduce risk of pneumonia shown by Warusevitaine et al. The one study included in this review found that PPI use in non-orally fed patients was significantly associated with increased risk of pneumonia while H2B was not, suggesting PPI may have to be avoided in those at high risk for pneumonia. There is equivocal evidence that NGT placement increases risk of SAP due to high degree of heterogeneity between studies. Further studies are needed to evaluate if treatment with H2B and PPI, and NGT use are implicated in the risk of SAP in patients with severe dysphagia.

A number of studies support the argument for a critical period of susceptibility for post-stroke infection (Langdon et al., 2009; Warusevitane et al., 2015; Hoffmann et al., 2017; Brogan et al., 2015). Warusevitaine et al. found of the patients that developed pneumonia, for 94% of patients this occurred within 7 days post admission; the mean time from NGT insertion to the first episode of pneumonia was 4 days in the treatment group and 2 days in the placebo group. Langdon et al. propose to hold off institutional enteral feeding for the first 3–4 days concentrating on maintaining hydration via intravenous or sub-cutaneous methods suggesting this may reduce the risk of post-stroke infection from stroke-induced immunodeficiency and allow spontaneous recovery of swallow function.

Both studies evaluating a MDT approach (Gandolfi et al., 2014; Aoki et al., 2016) to swallowing management found this impacted positively on reducing risk of incidence of SAP. This supports previous studies that have demonstrated an integrated team approach and dysphagia clinical pathway has a positive impact on rates of pneumonia (Hinchey et al., 2005; Palli et al., 2017; Perry and McLaren, 2000; Odderson et al., 1995; Odderson and McKenna, 1993). However, Aoki et al. lacked clarity about what the intervention involved. Improvement in pneumonia rates was attributed to increased oral care by dental professionals and instrumental assessments by SLPs, and the creation of appropriate dysphagia diets and nutritional supplements by dieticians. Similarly Gandolfi et al. lacked detail about what components of the intervention had a positive impact on patient outcomes. Both studies used either FEES and/or VFSS instrumental assessments and

emphasized the cooperation and utilization of different professionals. Additionally, the inclusion of an evaluation of postural control by Gandolfi et al. may have been a contributory factor to the success of the MDT management. However, it might be argued that in the Gandolfi study, dysphagia received greater attention in the T+ group with the implementation of the specific protocol rather than the protocol itself. The study also did not necessarily apply typical care routines within their teams, for example the rehabilitation physician rather than the SLP undertook the clinical bedside swallow assessment.

This review acknowledges certain limitations. There is a risk of selection bias. Studies were identified based on the selection criteria. We acknowledge that there are other studies that include dysphagic patients within unselected trial populations but because they did not report data specifically for this population, they were not retrieved by our search. For example, Anderson et al. (Anderson et al., 2017) examined whether lying flat versus sitting up at least 30 degrees as an early intervention in stroke care would improve outcomes in patients with ischemic stroke. There was no difference between the two groups in mortality (7.3% lying flat vs. 7.4% sitting up) or major disability (mRS 4–6) (38.9% lying flat vs. 39.7% sitting up). There was no significant between-group difference in the rate of pneumonia. However, data for patients with dysphagia were not reported which meant that this study would not have been retrieved by the search strategy. In this study, patients with a definite clinical indication or contraindication of being laid flat were excluded, such that patients with severe dysphagia may have been excluded. Other examples of selection bias were that only a small number of studies were identified which met the inclusion criteria for each factor and in some cases no relevant studies were found.

The pathoetiology of SAP is a combination of stroke-induced suppression of immune responses and pulmonary infectious challenge as a consequence of aspiration of oropharyngeal secretions and gastric contents into the lungs in the first few days post stroke. The Pneumonia in Stroke Consensus

(PIECES) group defines SAP as a spectrum of lower respiratory infections within the first 7 days after stroke onset and diagnosis of SAP are based on the Centers for Disease Control and Prevention (CDC) criteria (Smiith et al., 2015). Examples of reporting bias include variation in the diagnostic criteria for SAP and the period of diagnosis in the included studies. There may also be the possibility that non-infective causes of lung inflammation (e.g. pneumonitis) may have been reported as pneumonia. Further examples of reporting bias include the lack of information on the diagnosis and method of assessment of dysphagia and measure of severity. Therefore, the findings need to be interpreted with caution.

A further limitation was the sole use of British orthography for terms “oesophageal” and “GORD”. This may have precluded identification of some records using the American orthography. The use of the MeSH term “deglutition disorders” should have limited the impact of this omission.

2.2.5 Conclusion

This review has shown SAP is associated with a range of interventions and care processes and there is increased susceptibility in the acute phase for patients with dysphagia. Measures of immunodepression are associated with SAP in dysphagic patients. However, there is insufficient evidence to suggest screening for immunosuppression at this stage. There is absence of evidence that prophylactic antibiotics make a difference to pneumonia rates in patients with dysphagia and use of PPIs may be associated with increased risk. There is insufficient evidence to justify screening for aerobic Gram-negative bacteria. Treatment with metoclopramide may reduce SAP risk. A multidisciplinary team approach and instrumental assessment of swallowing may reduce risk of pneumonia. The evidence that NGT placement increases risk of SAP is equivocal. Impaired mobility is associated with increased risk. Further studies should examine these factors and the potential to reduce the incidence of SAP in patients with dysphagia using instrumental methods of assessment and standardized measurement criteria.

The supplementary material is available in the Appendix C – Supplementary Material for the Systematic Reviews (Page 297).

2.3 Summary of the literature since the publication of the systematic reviews

This summary provides an update of the evidence about the impact of dysphagia assessment and management, and medical interventions and care processes on risk of stroke-associated pneumonia in acute stroke. Two international guidelines (Dziewas et al., 2021a; Powers et al. 2018) and 8 studies (Han et al., 2018; Ouyang et al., 2020; Field et al., 2018; Nakamoiri et al., Teuschl et al., 2018a; Yuan et al., 2020; Cieplik et al., 2020; Inui et al., 2021) are included.

2.3.1 Dysphagia Screening

The American Heart Association/American Stroke Association (AHA/ASA) Guidelines for the Early Management of Patients With Acute Ischemic Stroke (Powers et al., 2018) and European Stroke Organisation (ESO) and European Society for Swallowing Disorders (ESSD) Guideline for the diagnosis and treatment of post-stroke dysphagia' (PSD) (Dziewas et al., 2021a) recommend dysphagia screening before the patient begins eating, drinking or receiving oral medications and early dysphagia screening can be effective to identify patients at higher risk for aspiration. The ESO-ESSD guideline recommends all patients with acute stroke, are screened with a formal dysphagia screening test as fast as possible. A water-swallow test or multiple-consistency test may be used.

Dysphagia screening compared to no screening was associated with reduced risk of pneumonia (OR 0.55 [0.36, 0.83]) and early dysphagia screening compared to late screening was associated with a significant reduction in pneumonia risk (9% vs. 15%) (OR 0.45 [0.35, 0.58]) (Dziewas et al., 2021a). The two most influential studies (Bray et al., 2017; Al-Khaled et

al., 2016) were included in the author's first systematic review (Eltringham et al., 2018). There were no comparative studies to determine whether dysphagia screening with multiple consistencies compared to screening with single consistencies reduce risk of SAP.

2.3.1.1 Type and Methods of Dysphagia Screening

Han et al (Han et al., 2018) undertook a registry-based, prospective cohort study using Sentinel Stroke National Audit Programme (SSNAP) data from four hyper acute stroke units in the Surrey region. A regional dysphagia screening protocol (DSP) was used. The DSP involved starting initially with 3 spoons of water and, if there was no risk of aspiration, 1 cup of water and then a trial of soft diet meal. The procedure was discontinued if there was a risk of aspiration at any stage of screening.

Ouyang et al. (Ouyang et al., 2020) used pre-defined secondary data from a multi-centre cluster cross-over, randomised controlled trial Head Positioning In Acute Stroke Trial [HeadPoST] to analyse association of dysphagia screening and SAP. The DSP was defined as the use of a simple, brief, non-invasive bedside test, such as drinking a sip of water. There was no detail regarding the type of DSP used. Multivariable analysis found no association between the use of a simple dysphagia screen and pneumonia ([aOR] 1.20, 95% CI 0.82-1.75). However, patients who failed the dysphagia screen had higher risks of developing SAP ([aOR] 3.00, 95% CI 2.18-4.10) compared to 'screen-pass' patients. The study had several limitations. There was potential for bias as participants were likely to have received greater attention to dysphagia monitoring and feeding actions because of the nature of the HeadPoST trial assessing the influence of head positioning on stroke outcomes. The HeadPoST trial also enrolled patients with predominantly minor strokes. This would have potentially influenced the profile of dysphagia patients in terms of their severity and consequently risk of SAP.

Two studies (Field et al., 2018; Nakamori et al., 2020) investigated cough reflex testing (CRT) and the impact on SAP in acute stroke. Nakamori et al.

(2020) used a prospective study and Field et al. (2018) employed a pragmatic randomised control trial. Field et al. found there was a non-significant reduction in pneumonia rates by 2.2% points in the CRT group (OR 0.32, 95% CI 0.06–1.62). In the study by Nakamori et al., the adjusted Cox proportional hazard model for pneumonia onset revealed that the simplified cough test had predictive power for pneumonia onset (hazard ratio, 10.52;95% CI, 3.72-29.72; p<0.001) and the authors recommended that the simplified cough test should be added to existing bedside screening tests for predicting pneumonia risk. Potential limitations of the study included exclusion of patients with severe stroke which may have led to sampling bias and no comparison was made between the simplified cough test with other instrumental swallowing investigations, for example, Fibreoptic Endoscopic Evaluation of Swallowing (FEES).

2.3.1.2 Frequency and Time of Screening

The frequency and timing of screening varied widely across regions in the study by Ouyang et al. (2020). The frequency of pneumonia was higher in patients who had a dysphagia screen compared to those who did not, and significantly higher in those who failed the screen, and it was associated with longer waiting times to having a dysphagia screen.

Han et al. (Han et al., 2018) used logistic regression to assess the risk (adjusted for age, stroke severity and co-morbidities) of delay in swallow screening on pneumonia. Compared with those who received swallow screening within 4 h of admission, a delay between 4 and 72 h was associated with greater risks of pneumonia: OR = 1.4 (95%CI:1.1–1.9, P = 0.022) and a delay beyond 72 h was associated with even greater risks of pneumonia: OR = 2.3 (1.4–3.6, P < 0.001).

2.3.2 Dysphagia Assessment

The ESO-ESSD guideline recommends all stroke patients who fail a dysphagia screen and/or show other clinical predictors of post stroke

dysphagia have a dysphagia assessment as soon as possible and, in addition to the clinical swallowing examination, VFSS or, preferentially, FEES should be available. The guideline also suggests that, in acute stroke patients, swallowing of tablets should routinely be evaluated as part of dysphagia assessment in addition to assessing the swallowing of liquid and different food consistencies and quantities. The AHA/ASA guidelines recommend an endoscopic evaluation for those patients suspected of aspiration to verify the presence/absence of aspiration and to determine the physiological reasons for the dysphagia to guide treatment plan.

2.3.2.1 Type and Method of Dysphagia Assessment

There was lack of detail about the type and method of dysphagia assessment used in the study by Ouyang et al. (2020). Dysphagia assessment was defined as a more systematic examination performed by a speech pathologist/therapist or qualified clinician, according to local standard protocols.

2.3.2.2 Frequency and Time of Assessment

In addition to the study by Bray et al. (Bray et al., 2017), which found a strong independent relationship between delays in dysphagia assessment and incidence of pneumonia, the ESO-ESSD guideline identified a retrospective chart review (Dhufaigh and Hayes, 2017). Dhufaigh and Hayes found that stroke patients receiving a clinical dysphagia assessment within 48 hours after admission had significantly fewer respiratory tract infections than patients seen post 48 hours.

Ouyang et al. (2020) analysed association of the detailed dysphagia assessment and SAP. The frequency of pneumonia was associated with longer waiting times to having a dysphagia assessment. Multivariable analysis found no association between the dysphagia assessment and pneumonia.

2.3.3 Dysphagia Management

2.3.3.1 Dietary modification

The ESO-ESSD guideline suggest that texture modified diets and/or thickened liquids may be used to reduce the risk of pneumonia and should be prescribed only based on an appropriate assessment of swallowing and patients on texture modified diets/and or thickened liquids should be monitored for fluid balance and nutritional intake. Meta-analysis of the literature found overall, dietary modifications were associated with a trend for a decreased risk of pneumonia (RR 0.19 [0.03, 1.40], p = 0.1).

Teuschl et al. (Teuschl et al., 2018a) conducted a retrospective database analysis of acute stroke patients and investigated how multi consistency dysphagia screening using the Gugging Swallowing Screen (GUSS) and dietary modifications affect the rate of SAP. Seventy-two patients developed SAP: 22/401 (5.5%) in patients without GUSS and 50/993 (5.0%) in patients with GUSS. For 20 of the 22 patients with SAP not tested with GUSS, reasons for non-testing were due to a combination of death, deterioration or impaired level of consciousness and being assigned NBM. In patients tested with GUSS, SAP was highest in patients with severe dysphagia (32/246, 13%) compared to patients with normal (0.8%), slight (2.4%) or moderate dysphagia (5.2%). Of the 50 patients who developed SAP: 3/50 were on normal diet and had no dysphagia, 3/50 were on a dysphagia diet of Level 5 Minced and Moist or Level 6 Soft and Bite Sized Diet; liquids thickened, Level 1 Slightly Thick or Level 2 Mildly Thick and had slight dysphagia, 9/50 were having a Pureed diet; liquids thickened, Level 2 Mildly Thick or Level 3 Moderately Thick and had moderate dysphagia, 3/50 were NBM except for crushed medications with apple sauce and had moderate dysphagia, 2/50 were NBM except for crushed medication and 30/50 were NBM and had severe dysphagia. Overall incidence of SAP was 5.2%, lower than reported pneumonia rates in other cited studies (Kishore et al., 2015; Westendorp et al., 2011). Teuschl et al. (2018a) suggest that dietary modifications recommended by GUSS may be successful in preventing SAP.

2.3.4 Medical interventions

2.3.4.1 NGT use

In Teuschl et al. (2018a) NGTs were significant markers for SAP. In the GUSS group, in 30 out of 50 cases (60%) SAP occurred despite patients being NBM, leading the authors to surmise that other factors may influence SAP in NGT fed patients including: oral bacteraemia, immobility or additional treatment with antibiotics. In a complementary poster presentation (Teuschl et al., 2018b), the authors suggest patients with severe strokes may benefit from an additional instrumental evaluation to decreases the use of NGT.

Ouyang et al. (2020) found patients who failed the dysphagia screen were more likely to be placed on feeding restrictions compared to those that passed the screen (84.1% vs. 11.2%, $p<0.0001$) and incidence of pneumonia were higher in patients that had feeding restrictions compared to those that did not (9.5% vs. 0.9%, $p<0.0001$).

2.3.4.2 Pharmacological treatment

Nakamori et al. (Nakamori et al., 2020) did not detect an association between medications (angiotensin-converting enzyme inhibitor, beta blocker, and cilistazol) and the results of simplified cough test or pneumonia onset.

2.3.5 Care processes

2.3.5.1 Oral care

The ESO-WSO guideline suggest implementation of oral health care interventions to reduce risk of pneumonia. The quality of the evidence for this recommendation was judged to be low and the strength of the recommendation was weak. However, it was judged that the risk of

intervention was very low and that its potential benefits outweigh the associated risks, which warranted a positive recommendation.

Yuan et al. (Yuan et al., 2020) conducted a pilot, single-blind, randomised controlled trial, and investigated the effects of intensified oral hygiene care (IOHC) on reducing stroke-associated pneumonia (SAP) incidence in 84 patients. In the routine oral hygiene care group, participants were asked to perform oral care by themselves, with or without the help of a nursing assistant. Those participants lacking the ability to perform oral care, received oral swabbing with saline (2-minute duration, twice daily). In the IOHC group, in addition to oral self-care (or instead of routine saline swabbing), all teeth and oral soft tissues, were swabbed with 0.12% chlorhexidine digluconate mouth wash (5-minute duration, 3 times daily). All interventions were performed by nurses who had been trained by a dental professional prior to the commencement of the study. SAP incidence was lower, though not significantly in the IOHC group than the control group (OR=0.349, 95% CI [0.118-1.033], P=.052). The results of subgroup analysis showed that the intervention significantly reduced the rate of SAP in participants who were male (OR=0.132, 95% CI [0.026-0.68], P=.008), had a higher NIHSS score (OR=0.246, 95% CI [0.068-0.897], P = .03), had a lower GCS score (OR = 0.15, 95% CI [0.029- 0.766], P = .017), had a lower GUSS score (OR = 0.227, 95% CI [0.057-0.913], P=.031), and had a higher Debris Index score (OR = 0.094, 95% CI [0.011-0.823], P = .013).

Cieplik et al. (Cieplik et al., 2020) undertook a prospective observational study that investigated the associations between dental/oral health with a specific focus on oral microbiota and incidence of SAP. Ninety-nine patients were included in the study which included a control group made up of stroke mimics (N=42), stroke patients without pneumonia (N=49) and stroke patients with SAP (N=8). The study involved 3 investigation timepoints: the baseline investigation within 24 hours of admission, and further investigation at 48 or 120 hours after baseline. Investigations included dental examination and microbiological sampling. Of the 57 patients diagnosed with stroke, 8 (14%) developed SAP. There were trends toward higher incidence of SAP in

patients with more missing teeth and worse oral hygiene. The major limitations of the study included the small number of patients in the pneumonia group and the inequitable distribution of patients among the groups, reducing the statistical power of the findings.

2.3.5.2 Pyriform Sinus Suctioning

Inui (Inui et al., 2017) conducted a single site quasi-experimental study to compare the incidence of pneumonia between before (control) and after (intervention group) intervention with daily pyriform sinus suctioning in 63 acute stroke patients during the first 5 days of hospital admission. Pyriform suctioning involved the insertion of catheter into the pyriform sinus from the corner of the mouth along the left or right lateral to posterior wall of the pharynx. Conditions for implementing suctioning were defined as periodic suctioning: suctioning 6 times/day at intervals of 4 hours after admission and additional suctioning when presence of wet coughs, wet hoarseness, and/or wet secretions involved in breathing. Incidence of pneumonia was 14.3% in the control versus 6.7% in the intervention group. Incidence of pneumonia between groups of patients at different risk levels, based on the Japanese Coma Scale, found SAP incidence was markedly lower in the intervention group among those with a low pneumonia risk, at 0%, ($p=0.06$). There were no significant differences between groups among those with high risk level. As an original intervention study conducted in a single facility, further research is needed to assess pyriform suctioning as an effective technique.

2.3.6 Conclusion

There is moderate quality evidence, and the strength of the recommendation is strong for screening all patients with acute stroke for dysphagia with a formal screening protocol as fast as possible after hospital admission before administration of food, fluids or oral medication. Those identified as having dysphagia should have a specialist swallow assessment as early as possible. There is insufficient evidence for use of cough reflex testing to compliment dysphagia screening to reduce SAP risk. The quality of the

evidence for use of texture modification and/or thickened fluids to minimise SAP was found to be low, although when balancing the benefits and risk of this intervention the European Swallowing Guidelines supplemented a cautious positive recommendation with a strong recommendation on the basis that these interventions are prescribed based on an appropriate assessment. The study by Teuschl et al., (2018a) which investigated the use of dietary modification and risk of SAP, was deemed to be the same low quality as the evidence about dietary interventions reviewed by Dziewas et al.

Teuschl et al. (2018a) identified that a high percentage (60%) of patients with SAP were NBM suggesting that NGTs were significant markers for SAP, and other factors such as oral hygiene and immobility may be contributing factors. This adds to the evidence base that a range of factors are associated with risk of SAP in patients with dysphagia (Eltringham et al., 2020). The European guidelines deemed there to be a lack in strength of evidence that oral healthcare is associated with reduced risk of SAP. The two studies (Yuan et al., 2020; Cieplik et al., 2020) identified in this review are consistent with this perspective. However, despite this equivocal or lack of evidence early NGT placement and oral intervention are recommended as the relative benefits are judged to outweigh the risks associated with these interventions, which is deemed to be low.

Two Japanese studies were included in this review. The first by Nakamoiri et al., was a single site study, and found no association between the use of angiotensin-converting enzyme inhibitors and pneumonia onset. The second a feasibility study by Inui et al. investigated pyriform sinus suctioning as an intervention to reduce SAP risk and found incidence of SAP was markedly lower among patients with a low level risk. The findings of both studies should be interpreted with caution.

In summary the recommendation to screen and assess all stroke patients as early as possible for dysphagia to reduce risk of SAP is strengthened by the updated international clinical guidelines. Further high-quality research is

needed to evaluate the impact of dysphagia management practices and medical interventions and care processes and their association with SAP.

Chapter 3 Methodologies underpinning the construction of the national survey

Introduction

This chapter sets out the justification for the methods chosen for Phase 2 of the programme of research, provides further detail about the philosophical assumptions and rationale for the choice of mixed methods design used to build the national survey. This chapter provides further detail on the use of the Sentinel Stroke National Audit Programme data for the mixed methods study.

3.1 Philosophical assumptions

The world view which best provides the foundations for the mixed methods study and mixed methods design is Pragmatism. Pragmatism is an overarching philosophy which combines the Post positivist and Constructionist world views. Pragmatism values both assumptions of interpretivist views (i.e. that reality is constructed by individuals) and positivist views that acknowledge these are reconstructions of something relatively stable that exists. Pragmatists emphasise the importance of empirical observation (positivist) but at the same time stress that these observations rely on the researchers' interpretations of these observations (interpretivism). Pragmatists recognise that there exist certain established stable social structures (positivist) but at the same time acknowledge that they are all of people in establishing and constructing these social structures (interpretivist).

A major underpinning of pragmatism epistemology is that knowledge is based on experience and experience cannot be separated from the social context in which those experiences occur. As a philosophical foundation for mixed methods research, pragmatism fits with the real-world experiences of the researcher who is also as a speech and language therapist (SLT) who works within a hospital setting. Clinically in the assessment and management of dysphagia, knowledge will be obtained from different sources and types of

information and data. For example, the written report from objectives tests such as a Computed Tomography (CT) of the head and Magnetic Resonance Imaging (MRI) of the head, which is presented in a formal rhetoric, will inform the likely pattern of dysphagia based on the location and severity of the stroke and the SLT will use this information in combination with other test results to deductively reason how the patient might present at bedside. Information provided by the patient and carer about the patient's previous medical history including any chronic swallowing difficulties and the history of the current difficulties will be the patient's story and the assessor will develop subjective meanings from the phenomena described. This in combination with the information from the clinical swallowing examination will inform the clinician's hypothesis generation and management recommendations.

The notion that paradigms or world views can be related to the study context and type of mixed methods design is embraced by Creswell and Plano Clark (2018). Phase 2 incorporates an all-encompassing worldview that enables gathering all types of data that best answer the research question. This practical but intuitive approach helps to offer multiple ways of viewing the research problem that is found in clinical practice. It also acknowledges the researcher's beliefs about the acquisition of knowledge and that multiple worldviews can be in dialogue or situated at different phases of a study or during a programme of research instead of a single world view.

3.2 Rationale for using Mixed Methods to answer clinical questions

Bryman (Bryman, 2006) identifies a number of rationales for combining qualitative and quantitative research and made a distinction between rationale and practice, as researchers were observed to find more uses for mixed methods research in practice. The researcher's reasons for using mixed methods are discussed here and include developing the survey instrument (3.2.1); the research question (3.2.2); reciprocity (3.2.3); triangulation (3.2.4); and diversity of views (3.2.5). Bryman (Bryman, 2006) identified 'offset' as a reason to use mixed methods which refers to when the

limitation of one method can be offset against the strength of another. The national survey content is strengthened by using these components to make up the whole.

3.2.1 Developing the survey instrument

The fundamental reason for using mixed methods was to develop a survey instrument. Bryman (Bryman, 2006) uses the term ‘instrument development’ in the context of an exploratory mixed methods design where the qualitative component is used to develop a questionnaire. In this study the quantitative and qualitative data were analysed separately. The findings from these analyses were then integrated, as part of the convergent design, to develop the national survey.

3.2.2 Research question

The ‘multi-faceted question’ reflects the multifactorial cause of SAP and the inter-professional approach to the assessment and management of swallowing. Choosing mixed methods has best enabled the researcher to get to the truth and collect the best data for the research project by providing the multiple perspectives required to investigate the research topic.

3.2.3 Reciprocity

Sieber (Sieber, 1973) in his writings about the integration of fieldwork and survey methods identified the integration of research techniques can provide enormous opportunities for mutual advantages in the research design, data collection, and data analysis phases of the research process. In the design stage, the case note review assisted ‘sampling’ by identifying representative patient and carer sample members for the interview study. In practice preliminary analysis from the quantitative data were able to shed new light on the interview topic guide for the staff interviews. The staff interviews which made up the convergent design also contributed to the design of the survey data collection instrument (Phase 3). The exploratory interviews which

preceded the survey gave valuable insight into the receptivity and frames of reference of the potential survey respondents such as broadening or narrowing the salient topics.

3.2.4 Triangulation

Triangulation is when data from multiple methods is converged in order to provide greater validity. A further motivation for using mixed methods was the sense that a more complete and comprehensive understanding of the problem would be achieved when both quantitative and qualitative methods were employed. For example, the case note review would give a detailed understanding of the clinical realities of dysphagia assessment within the first 72 hours, whilst the interviews would provide insights into peoples' perceptions of current practice and variations in organisational approaches, complementing the facts-based data available from the case notes.

3.2.5 Diversity of views

The semi-structured interviews gave access to the perspectives of staff who are responsible for screening, assessing and managing dysphagia in stroke patients and the topic guide was orientated to organisational practice. The patient interviews explored the experience of people who had their swallowing assessed. These data were needed to amplify the quantitative data from the cases notes which investigated performance against key performance indicators and specified criteria.

3.3 Rationale for the choice of Convergent Mixed Methods design to build the survey content

A mixed methods convergent design was chosen for this study (Creswell and Plano Clark, 2018). The rationale for this approach was to obtain different but complimentary data on the same topic to best understand the research problem. Quantitative and qualitative data about the topic are collected concurrently and separately, and the two data sets are analysed

independently using quantitative and qualitative analytic procedures. When analysis is complete the two data sets are brought together and compared for a more comprehensive understanding of the research problem. Finally the researcher interprets to what extent and in what ways the two sets of results agree or disagree, to create a better understanding in response to the study's overall purpose. The way in which this was enacted for this programme of research is detailed in Chapter 6 Survey Results.

3.4 Use of SSNAP data for the Mixed Methods studies

3.4.1 Case note review of 30 stroke patients screened and assessed for dysphagia on admission to hospital (Phase 2)

The following SSNAP Domain 4 Specialist Assessment Key Indicators were used to measure delivery of these interventions versus the recommended standards of care: **4.5B Percentage of applicable patients who were given a swallow screen within 4h of clock star**t and **4.6B Percentage of applicable patients who were given a formal swallow assessment within 72h of clock start**.

The data on the SSNAP register for these Specialist Assessment Key Indicators and percentage of antibiotics prescribed for a newly diagnosed pneumonia within the first seven days of hospital admission were compared with the data collected for these measures in the case note review for consistency of reporting.

3.4.2 Site selection for the staff interviews (Phase 2)

The rationale for site selection for the staff interviews were based on hospitals registered on SSNAP from the Yorkshire and The Humber Strategic Clinical Network (SCN), East Midlands SCN, Lancashire and South Cumbria SCN and London SCN. These SCN regions were selected based on their geographical proximity to the host institution and representative of centralised versus non centralised models of acute stroke care. Hospital

sites for participant recruitment were identified based on comparable size to the host site for the research and which performed differently in terms of the maximum variation of percentage of antibiotics for a newly acquired pneumonia with the first seven days of hospital admission and performance against SSNAP Domain 4 Specialist Assessment Key Indicators: 4.5B and 4.6B.

Sites were selected based on the April 2015-March 2016 SCN's composition: Yorkshire and The Humber SCN (14 hospitals), East Midlands SCN (7 hospitals), Manchester, Lancashire & South Cumbria SCN (N=7 hospitals) and London SCN (8 hospitals). The following variables were analysed for the data periods April 2015-March 2016, April-July 2016 and August-November 2016 using Team Centred data: percentage of antibiotics for a newly acquired pneumonia in the first 7 days from clock start, percentage of patients who were given a swallow screen within 4h of clock start and percentage of applicable patients who were given a formal swallow assessment within 72h of clock start. There were differences in composition of the hospitals in the SCNs across the time periods. An initial +/- 10% of number of stroke patient admissions compared to the host site for site identification was widened to +/- 15% as there were insufficient sites at the 10% level. Two outliers (St. George's Hospital London and Salford Royal Hospital) which just fell outside the +/- 15% were included which gave a sample pool of ten sites (excluding the host site). Descriptive statistics were undertaken using Microsoft Excel to identify +/- percentage points differences compared to Royal Hallamshire Hospital (RHH) for the different variables. Based on this analysis St George's (London SCN), Leicester Royal Infirmary (East Midlands SCN), Fairfield General Hospital (Manchester, Lancashire & South Cumbria SCN) and Hull Royal Infirmary (Yorkshire and The Humber SCN), were identified as the preferred sites for the staff interviews.

Chapter 4 Results of the underpinning studies

Introduction

This chapter describes the detail of the methods and results of Phase 2 of the programme of research, the mixed methods studies. There are three components to this phase: a quantitative study (the clinical audit of case notes) and two interview studies. The timing of the clinical audit and the patient and staff interview studies occurred sequentially with the interviews following on from the case note review. The case note review aimed to provide detailed understanding of dysphagia management during the first 72 hours from of a stroke patient's admission, while the interviews aimed to provide insights into current practice not readily available from quantitative data.

The findings of the clinical audit were presented as a written report to the hospital Clinical Effectiveness Unit. Some sections of this chapter are reproduced from the report, and this is highlighted before each section where this occurs. Other sections have been expanded to provide further detail specifically about data abstraction and analysis (4.1.3.1) and the pilot phase (4.1.3.2). The researcher reflects on the potential blurring of researcher and clinical boundaries during data collection, the generalisability of the results, and expands on the dissemination of the results.

The two interview studies were published in the international peer reviewed journal 'Geriatrics'. The staff interviews 'Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study' belongs to the Special Issue 'The Rehabilitation and Management of Dysphagia' (Eltringham et al., 2019a). A sister paper about the patient-carer interviews was published in the Special Issue 'Stroke in the Elderly' (Eltringham et al., 2019b). Some of the methods of how patients and the public were involved in the analysis and interpretation of the research data are set out in the published paper 'Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers'. Additional detail about Patient and

Public Involvement (PPI) is provided, including the dissemination of the research findings.

4.1 Clinical Audit: Case Note Review

The primary aim of the case note review was to inform the question objectives as part of the development of the national survey. A secondary aim was to identify potential participants for the patient interviews. The audit permitted a deeper dive beneath the performance scores against the Sentinel Stroke National Audit Programme (SSNAP) standards, to understand factors that may contribute to risk of stroke-associated pneumonia (SAP) during the first 7 days of admission post stroke. At a local hospital level, the audit aimed to identify reasons why SSNAP standards for dysphagia screening and assessment were not being met and to identify any discordance in reporting with the SSNAP database.

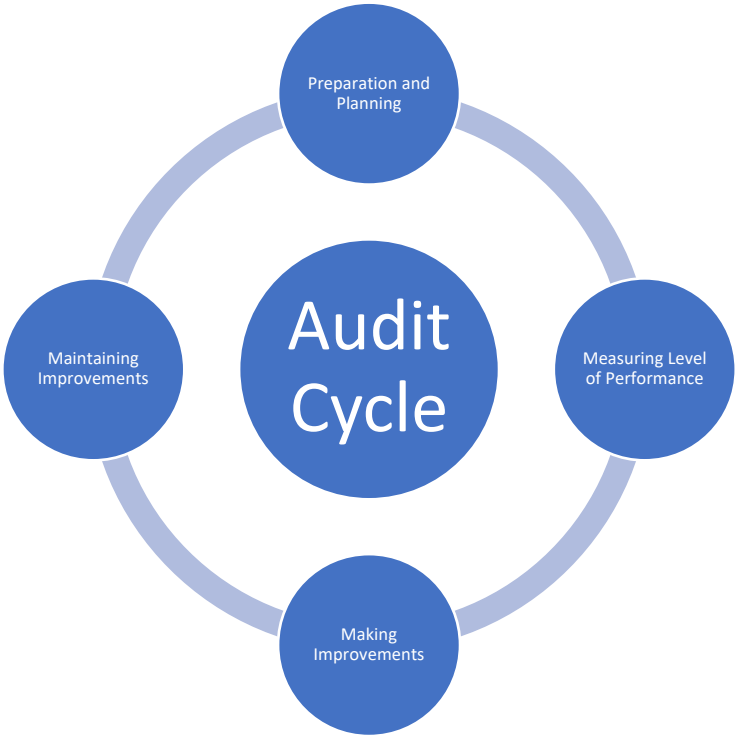
4.1.1 Clinical Audit and the Audit Cycle

Clinical audit is defined as a quality improvement cycle shown in Figure 4.1 The Audit Cycle. It measures the effectiveness of healthcare against agreed and proven standards for quality, and taking action to bring practice in line with standards so as to improve the quality of care and health outcome (Burgess and Moorhead, 2011). Clinical (or medical) audits are part of the continuous quality improvement process that focus on specific issues or aspects of health care and clinical practice. They consist of measuring a clinical outcome or process against well-defined evidence-based clinical standards. The aim of the audit is to highlight discrepancies between actual practices with standards, to identify the action needed to improve the quality of care.

Clinical audit consists of a “quality loop”(Esposito and Dal Canton, 2014). The main stages of clinical audit are: selecting the topic, agreeing standards of best practice, collecting data on current practice, analysing data against the standards, feeding back on the results and implementing changes,

allowing time for changes to embed before re-auditing, and then beginning the cycle again. The results of the re-audit are analysed to see whether practice has improved.

Figure 4.1 – The Audit Cycle (www.hqip.org.uk)



4.1.2 Aim and objectives

Section 4.1.2 Aim and objectives is reproduced from the report submitted to the hospital Clinical Effectiveness Unit on a case note review about hospital performance on SSNAP Domain 4 Specialist Assessment Key Indicators.

4.1.2.1 Aim

To ensure dysphagia screening and specialist speech and language therapy swallow assessments are carried out within their performance timescales and improve awareness of how factors in acute care may increase risk of stroke-associated pneumonia (SAP).

4.1.2.2 Objectives

1. To determine the proportion of patients receiving a swallow screen according to guidance set out by the Royal College of Physicians (RCP) Clinical Guideline for Stroke (Criteria 1).
2. To determine the proportion of patients receiving a Speech and Language Therapist (SLT) swallow assessment according to guidance set out by the RCP Clinical Guideline for Stroke (Criteria 2).
3. To ascertain whether the timing of the swallow screen and SLT swallow assessment, and prescription of antibiotics for newly acquired pneumonia in the medical notes matches the SSNAP data (Criteria 3-5)
4. To ascertain proportion of patients admitted by day of week.
5. To ascertain proportion of patients who are admitted directly to the Hyper Acute Stroke Unit (HASU).
6. To ascertain staff grade undertaking the screen.
7. To ascertain possible explanations to why the performance targets relating to timing of screen and SLT swallow assessment were not achieved.
8. To determine the outcome of screen.
9. To determine length of time the patient was Nil by Mouth (NBM) before nasogastric tube (NGT) passed.
10. To determine what NGT feeding regime was prescribed.
11. To determine proportion of patients who are prescribed intravenous (IV) fluids during the first 72 hours of admission.
12. To determine proportion of patients who are NBM who are prescribed mouth care.
13. To determine proportion of patients who are referred to SLT following the screen.
14. To determine proportion of patients who pass their swallow screen and are subsequently referred to SLT for a swallow assessment within first 72 hours of admission.
15. To determine reason for referral for a SLT swallow assessment for patients who initially passed the screen.
16. To ascertain grade of SLT completing initial SLT swallow assessment.
17. To determine the recommendations of the SLT swallow assessment.

18. To determine what proportion of diet and feeding regimes made following the screen are downgraded after the SLT swallow assessment.
19. To ascertain level of adherence to recommendations following swallow screen and SLT swallow assessment.
20. To determine the proportion of patients receiving an instrumental swallow investigation and what type during the first 72 hours of admission.
21. To determine proportion of patients prescribed acid suppressive medication.
22. To determine proportion of patients prescribed angiotensin-converting-enzyme (ACE) inhibitors.

4.1.3 Methods for case note review

The case note review took place in a large NHS teaching hospital. The project was registered and approved by the hospital Clinical Effectiveness Unit. The sample size of thirty medical notes of patients who had a dysphagia screen on admission and who subsequently had a swallow assessment was based on a representative sample of the population of stroke patients who are admitted to the Hyper Acute Stroke Unit and referred to the Speech and Language Therapy Service over a 6-week period. The sample size and length of data collection was determined by combining two sources of information: a previous SLT service exercise to monitor the monthly rate of SLT stroke hospital referrals, and advice provided by the Clinical Effectiveness Unit. A period of six weeks was deemed to be long enough to allow for fluctuations in admission rates and was a reasonable number of admissions within the timescale of the research to provide the snapshot of clinical service needed for the audit.

Medical records were identified, using the Stroke Tracker (a live document for recording stroke patient admission) which allowed consecutive admissions to be selected for potential case note review. Patients who passed the dysphagia screen continued to be monitored for 7 days via SystmOne (a clinical computer system) to check whether the patient was

subsequently referred for a specialist swallow assessment. Admissions were monitored until the target sample of thirty patients was reached.

As well as the 30 case notes, this study also wanted to identify 5 stroke patients who fulfilled the criteria of having a dysphagia screen on admission and who went onto have a swallowing assessment by a SLT or equivalently trained professional.

4.1.3.1 Data abstraction and analysis

Paper based sources of data were the patient Stroke Nurse Specialist/HASU Nurse Assessment, dysphagia screen, medical notes, drug card and dietitian regime card. Electronic data sources included SystmOne, Lorenzo; which is a patient record system, and the SSNAP database. A data extraction form was set up using Microsoft Excel. Questions to ask of the case notes were based on the SSNAP Key indicators for a) timing of the swallow screen and b) specialist swallow assessment, c) percentage of patients prescribed antibiotics for a new acquired pneumonia during the first 7 days of admission and d) consistency of audit findings with what is recorded on the SSNAP database for Key indicators a), b) and c). Additional data were collected on 1) admission process, 2) grade of staff undertaking the assessment, 3) assessment outcome and 4) information relating to care processes and medication interventions, which are elements of care identified from the literature as important variables (Eltringham et al., 2018; Eltringham et al., 2020; Beavan, 2015; Arai et al., 2017; Alsumrain et al., 2012). Microsoft Excel and SPSS were used to analyse the data. Descriptive statistics were used to understand and describe the features of the data.

A risk assessment form was completed to identify potential risks and who may be at risk, based on the hospital Guidelines for Completing a Risk Assessment Form. This was completed in conjunction with the hospital Care Group Risk Lead.

4.1.3.2 Piloting the data collection tool and collection methods

The pilot phase assessed the functionality of the data collection tool, the recording method, checked that data sources were available and were accurate and provided a more reliable time estimate for the main data collection. The sample size for the pilot were five patient medical records.

The pilot phase ran for two weeks in the autumn/winter of 2017. Based on the length of time it took to reach the target sample, this translated to an estimated period of seven weeks for the main data collection. The pilot identified an unanticipated delay in the uploading of the data on the SSNAP database for the recording of prescription of antibiotics for a newly acquired pneumonia in the first 7 days of admission. If the patient remained an inpatient, these data were not inputted until the patient has transitioned through their acute hospital stay. This would potentially impact on when the analysis for the main data collection could be completed and the end date of the project.

The pilot highlighted several practical considerations for the main data collection. Data collection was time consuming, requiring the researcher to visit wards in the evenings and weekends to confirm if the patient admitted was identified as having had a stroke or not and record information before the patient was discharged. This was done to avoid recalling medical notes retrospectively which would have slowed up the data collection process. The pilot identified some patients who may have been on antibiotics, acid suppressive medications, or ACE inhibitors pre-admission and highlighted the potential for this to be a confounding factor in the development of SAP.

There was potential for variation in data sources for some items. For example, the time recorded on the dysphagia screen was used as the primary source for the time of the dysphagia screen. However, this was not always consistent with the time recorded on the Stroke Nurse Specialist/HASU Nurse Assessment. This latter recorded time was the main data source for the time of screen for the Stroke Data coordinator who inputs

the data on the SSNAP database. To resolve this, the dysphagia screen was used as the primary source for the audit but, if the time was missing, then the Stroke Nurse Specialist/HASU Nurse Assessment was used. If there was a difference in time between the two sources but both were within the 4-hour target, then it would be recorded as consistent with SSNAP. Any missing data on the Stroke Nurse Specialist/HASU Nurse Assessment such as admission time was sourced from Lorenzo. The Stroke Nurse Specialist/HASU Nurse Assessment was used as the primary source of information relating to the admission process.

Identifying the data source for each item was included as a separate worksheet in the data collection tool. Collecting the data source for each item proved time consuming and was identified as a potential source of error as it required switching between two excel worksheets. Once the data source had been established from the pilot, the source of data was not collected for the main data collection.

The following amendments were made to the data collection tool following the pilot:

1. An additional question: “Did the patient vomit as part of their presenting complaint? This was identified as a possible contributing factor to pneumonia at the 2017 UK Stroke Forum Conference.
2. To be consistent with the SSNAP web tool, an additional response option “No – Valid Reason” was inserted for Criteria 1 and Criteria 2 to account for patients who were not sufficiently alert or medically unwell to be screened/assessed.
3. The question relating to Objective 10 (To determine what Nasogastric tube-feeding regime was prescribed), was amended to “What initial feeding regime was prescribed?” as the pilot identified that the feeding regime could change within the first 72 hours of admission. A date of NGT insertion as well as the time was recorded, as the NGT may not be inserted on day of admission.

4. The question relating to Objective 12 (To determine proportion of patients who are NBM who are prescribed mouth care) was amended to “If the patient was NBM, were they prescribed mouth care QDS i.e. four times a day, on SNS/HASU Nurse Assessment proforma?”. This amendment was made in order to be consistent with Stroke Nurse Specialist/HASU Nurse Assessment.
5. Dysphagia Trained Practitioner (DTP) was included under what grade of staff undertook the initial SLT assessment.
6. Certain questions were streamlined by theme with sub questions rather than separate questions.
7. Swallowing trials were included as an option for recommendations following the initial SLT assessment.
8. The question relating to referral to SLT during admission was amended to during the > 7 days of admission.
9. The questions relating to objectives 21 and 22 were changed to new prescription of acid suppressive medications and ACE Inhibitors.

4.1.4 Results

Data were collected over a six-week period in early 2018. This timeframe coincides in the United Kingdom with annual winter pressures on hospital admissions.

4.1.4.1 Admission process

Seventeen of the 30 (57%) patients were admitted on a weekday compared to 13 (43%) of patients admitted at the weekend. The highest number of patients (8/30) were admitted on a Sunday. Twenty-four (80%) patients were directly admitted to a stroke bed, with 3 (10%) being admitted via Accident and Emergency (A&E) which is located at a different hospital site to the Hyper Acute and Acute Stroke Unit. Three (10%) patients were admitted via another ward. Four patients (13%) were recorded as having vomited as part of their presenting complaint.

4.1.4.2 Swallow Screen

On admission 28 out of 30 (93%) patients received a swallow screen. Two patients (7%) were not screened. In 27 cases (90%) there was documentation on who undertook the screen. A qualified nurse performed 15 out of 27 (56%) of screens compared to 12 (44%) which were undertaken by a Dysphagia Trained Practitioner (DTP) stroke nurse who completed a comprehensive swallow assessment. Fourteen patients (47%) had their swallow screened within 4 hours of admission (Table 4.1). In 15 out of 16 patients the reason for patients not being screened were not being sufficiently alert or medically unwell (5/15, 33%); delayed arrival to a stroke bed (4/15, 27%); organisational resources (4/15, 27%); or being off the ward for medical investigations (2/15, 13%). Excluding the patients who were medically unwell increased the percentage of patients who had a swallow screened within 4 hours to 14/25 (56%).

Outcome of screen

Of the 28 out of 30 (93%) patients who had a screen, 15 (54%) were recommended Nil by Mouth (NBM) and 3 (11%) commenced swallow trials. Four patients (14%) passed the screen and were able to eat and drink as normal and 6 patients (21%) were recommended normal fluids and a modified diet, such as puree or a soft diet.

Twenty patients (67%) were prescribed intravenous (IV) fluids within the first 72 hours of admission.

The length of time between patients placed Nil by Mouth and having a nasogastric tube (NGT) insertion was not consistently documented. The initial feeding regime was documented for 12 patients. Five of the twelve (42%) patients commenced the out of hours 20 hours continuous feeding regime. Continuous feeding is given by pump over a long period of time, compared to the bolus method (where a syringe is used to send formula

through the feeding tube). Five (42%) were prescribed the continuous feed by the dietician and 2/5 (16%) patients were prescribed bolus feed.

In no cases where the patient was recommended NBM was it documented in the Stroke Nurse Specialist/HASU Nurse Assessment that the patients should be prescribed mouth care.

4.1.4.3 Formal Swallow Assessment

Twenty six of the 28 patients (93%) had a comprehensive swallow assessment following their swallow screen. Four patients were subsequently referred to SLT for a swallow assessment: 3 for adverse signs to indicate aspiration and 1 due to extension of stroke. The referral of these four patients accounted for the total sample of thirty patients who had a comprehensive swallow assessment. Twenty-six out of 30 (87%) had a comprehensive swallow assessment within 72 hours of admission. Compliance with the audit standards is presented in Table 4.1. Seventeen (57%) of the specialist swallow assessments were undertaken by a DTP Stroke Nurse. Eight (27%) were undertaken by Band 6 SLTs and 5 (16%) by Band 7 SLTs.

Outcome of swallow assessment

Thirteen out of 30 (43%) patients were recommended NBM following assessment. In order of frequency, the remaining patients were recommended: thin fluids and a modified diet (6/30), modified fluids and diet (6/30), normal fluids and a soft-normal diet (2/30), swallow trials (2/30) and modified fluids and soft-normal diet (1/30). Of the initial 28 patients who had a swallow screen and then a formal swallow assessment, for 15 patients (54%) the recommendations did not change. In 10 (67%) of these patients, the recommendations remained the same because the DTP stroke nurse did the initial swallow assessment. In 7 (25%), the recommendations from the screen were upgraded (that is, the level of modification to diet and fluid were reduced) compared to 6 patients whose recommendations were downgraded

(that is, the original diet and fluid recommendations required further modification).

Table 4.1 – Compliance with the audit standards

Criteria for dysphagia assessment and consistency of reporting with what is recorded on the SSNAP database		Target standards	Compliance with standards Numbers and %
1.	Patients with acute stroke should have their swallow screened, using a validated screening tool, by a trained healthcare professional within 4 hours of arrival of hospital and before being given any oral food, fluid and medication.	100% of patients will have their swallow screened within < 4 hours of admission.	14/30 (47%)
2.	Patients who are at risk of dysphagia (i.e. identified from the swallow screen) should have a formal swallow assessment < 72 hours of admission	100% of patients identified as at risk of dysphagia from the screen have a formal swallow assessment < 72 hours of admission	26/30 (87%)
3.	Time of screen recorded on SSNAP data register for patients who have had their swallow screen is consistent with what is recorded in the patient's medical notes	In 100% of cases the time of dysphagia screen recorded in medical notes and on SSNAP register shall be the same	27/30 (90%)
4.	Time of comprehensive swallow assessment recorded on SSNAP register for patients who have had their swallow assessed is consistent with what is recorded in the patient's medical notes	In 100% of cases the time of comprehensive swallow assessment recorded in medical notes and on SSNAP register shall be the same	13/30 (43%)
5.	Documentation of prescription of antibiotics for newly acquired pneumonia recorded on SSNAP data register is consistent with what is recorded in the medical notes.	In 100% of cases if relevant, the prescription of antibiotics for newly acquired pneumonia documented in the medical notes is the same as recorded on SSNAP	22/30 (73%)

4.1.4.4 Medical interventions and care processes

Eleven of the 30 patient (37%) were prescribed antibiotics for a newly acquired pneumonia in the first 7 days of admission.

Nine (30%) were prescribed newly prescribed acid suppressive medications and, in all cases, these were proton pump inhibitors (PPIs) as opposed to histamine 2 blockers (H2Bs). This difference was checked as there is an increased risk of SAP in patients with dysphagia in patients on PPIs compared to H2Bs (Eltringham et al., 2020). Two (7%) patients were given newly prescribed ACE inhibitors.

No Fibre Optic Endoscopic Evaluation of Swallowing (FEES) or Videofluoroscopy (VF) investigations were performed within the first 72 hours of admission.

There were 3 (10%) cases of non-adherence to recommendations following the dysphagia screen and specialist swallow assessment. In two cases, this related to patients pulling out their NGT and one related to adherence to the fluid recommendations.

4.1.5 Identification of Interview Participants

Seven patients were identified as potential interview participants. Patients who died or who were not appropriate to interview, due to severe cognitive impairment or medical status were excluded. Three patients declined to take part and one did not respond to the participant invitation letter.

In order to meet the target sample, and with the agreement of the audit team, the case note review was extended until the target sample of five patients was reached and a further 2 participants were recruited.

4.1.6 Risk Assessment of Clinical Outcomes

Two risks were identified: Risk to the patient and risk to the Trust. Risk scores were calculated based on measures of consequences and the likelihood of the consequences with existing controls in place.

4.1.6.1 Risk to Patient

The potential consequence for the patient who does not have a swallow screen within the target timescale is that there is an increased risk of pneumonia (Bray et al., 2017) or increased risk of choking. The patient risk score was lower than first appears as there was a valid reason in 5 of the 30 cases to not perform the swallow screen.

4.1.6.2 Risk to the Trust

There are two risks of reputational damage to the Trust: potential harm to patients can give rise to complaints, claims or other actions and the SSNAP audit is used as a quality indicator.

4.1.7 Action Plan

The action plan consisted of registering the risk on the Trust web-based incident reporting system and the revision of the audit standards to account for patients appropriately excluded due to being medically unwell. Other actions included improving staff awareness amongst Nursing Staff of the RCP Stroke Guidelines and risks associated with dysphagia in SLT training courses including the Newly Qualified Nurse Practitioner Induction and Preceptorship Training Programme and Dysphagia Screener Training. The Stroke Nurse Consultant took responsibility for the actions to ensure that there were a minimum number of trained staff to screen patients on admitting wards and to monitor numbers of staff trained to screen patients for dysphagia. Additional responsibilities of the Nurse Consultant were to raise awareness amongst the Nurse Directors and Matrons of the importance of

SSNAP targets, and risk of stroke patients not being screened particularly in patients not directly admitted to a stroke bed, and to raise awareness of the RCP Clinical Guideline for Stroke at training events and meetings.

The audit cycle was repeated allowing time for actions to be implemented and changes to embed. The findings of the repeat audit were not part of this research project.

4.1.8 Discussion

This section (4.1.8) is reproduced from the report submitted to the hospital.

4.1.8.1 Performance vs. Criteria

Criteria 1 - 100% of patients will have their swallow screened within < 4 hours of admission.

Of the 16 patients (53%) who did not have their swallow screened within the 4h target, there was a valid reason in 5 cases (17%). For the remaining patients, the main reasons for not meeting the 4h target were a combination of delay in patients arriving to a stroke bed and organisational resources. The timing of the case note review also coincided with winter pressures and a high proportion of patients being admitted at the weekend, putting increased pressures on organisational resources.

In one case, a patient who had been eating and drinking since admission had a choking episode resulting in a cardiac arrest call. The patient had been observed to eat and drink by a qualified dysphagia screener and documentation stated that the patient was for normal diet and thin fluids. The dysphagia screen protocol had not been completed.

In another example, documentation showed that that a dysphagia screen had been carried out (no time recorded) and the patient was recommended normal diet and fluids. No dysphagia screen protocol was found in the

medical notes. The patient was referred two days later for a specialist swallow assessment due to signs of potential aspiration.

Criteria 2 - 100% of patients identified as at risk of dysphagia from the screen have a formal swallow assessment < 72 hours of admission.

Of the 4 patients (13.3%) who did not have a formal swallow assessment within 72 hours there was a valid reason in 3 patients (10%) and included: patient off ward for emergency scan and patients initially passing the screen and being referred 72 hours post admission.

Criteria 3 - Differences of time of screen vs. SSNAP (N=3).

Differences were due to inconsistencies in time documented on screen compared to what was recorded on the Stroke Nurse Specialist/HASU Nurse Assessment and reason given for target not being met.

Criteria 4 - Differences of time of SLT assessment vs. SSNAP (N=17).

In the majority of cases (14/17), the difference was due to the DTP Stroke Nurse initial assessment not being counted as the initial swallow assessment and reason given for target not being met. The main reason for the DTP initial assessment not being counted was that it was not recorded in Stroke Nurse Specialist/HASU Nurse Assessment documentation. This did not reflect the timeliness of when patients receive a comprehensive swallow assessment and affected the <72 h target in 4 cases. In 2 cases, the reason given for the patient not being seen within 72 hours of admission was ‘Organisational Resources’. However, in one case the patient had initially passed the screen therefore ‘No relevant deficit’ would have potentially been a more appropriate reason and, in another, the patient was off the ward and then unwell.

Criteria 5 – Differences of prescriptions of antibiotics for newly acquired pneumonia on SSNAP vs. medical notes (N=7).

Antibiotics usage appeared to be under reported compared to SSNAP. For the purposes of the Case Note review, medical notes and the patient's drug card were reviewed. Potentially, if the correct information is not recorded in the Stroke Nurse Specialist/HASU Nurse Assessment, then the non-clinically trained person responsible for inputting into the SSNAP data base would not necessarily have the knowledge to review the medical notes or drug card.

4.1.8.2 Further discussion

The high percentage of initial swallow assessments undertaken by the Dysphagia Trainer Nurse Practitioner (DTP) Stroke Nurses emphasises the importance of their role locally to ensure that patients are assessed in a timely manner. This was more apparent over the audit period due to the high volume of patients admitted over the weekend when there is no SLT cover. The profile of admissions by day of week also underlines the importance of having sufficient flexibility in SLT staffing on Fridays to see any new referrals for swallowing and communication, which may breach the SSNAP target if not seen until after the weekend and the Monday, due to the high number of week-end referrals. Recent evidence has demonstrated that early dysphagia screening and specialist swallow assessment by a SLT has shown to reduce the risk of SAP, (Al-Khaled et al., 2016; Bray et al., 2017) and that delays in SLT assessment were associated with SAP, with an absolute risk of pneumonia incidence of 1% per day of delay.

No instrumental investigations of swallowing were performed during the first 72h of admission. Being physically well enough to attend a VF appointment and availability of the one in-patient VF slot a week may preclude patients from attending. However FEES has the advantage of being able to be performed at bedside. This valuable resource is potentially underutilised in patients identified with severe dysphagia. In one patient, a FEES was recommended on Day 4 post admission. The FEES examination did not

happen until nine days later. Potential reasons for this delay include: medical status of the patient and the appropriateness of an invasive investigation of a patient who had a recent cardiac arrest; delay in actioning the recommendation for the FEES referral by the SLT; the availability of the FEES appointment; and organisational resources to undertake the FEES. Currently there is only one weekly in-patient FEES appointment in the hospital, and it requires the availability of two SLTs: one to pass the scope and the other to interpret the investigation.

Twenty per cent of the sample was not directly admitted onto a Stroke ward. Delays in arriving to a stroke bed were one of the main reasons for the 4h target not being met. This emphasises the importance of having sufficient dysphagia trained staff located in A&E and the flexibility for trained screeners to go to outlying wards to screen patients within the 4h target. This review also highlighted that not all staff may be aware of the RCP Guidelines that all patients must be screened before having any oral intake or medications.

In NGT-fed patients, if nursing staff are unable to aspirate gastric contents using an irrigation syringe, a Chest X Ray (CXR) is requested to check the position of the NGT to make sure it is correctly sited. Patients can have multiple CXRs in the first week. In one example, a patient attended CXR on 5 consecutive days to check the NGT position and had also attended on the same day for another reason. The safety of patients is paramount. However, throughout that time, delays in NG feeding mean patients are not having any consistent source of nutrition (Quek et al., 2018), and patients are having repeated X Ray exposure.

A number of studies have suggested medications such as ACE-inhibitors and acid suppressive medications may be associated with pneumonia (Caldeira et al., 2012; Arai et al., 2017). Taking ACE-inhibitors may enhance the cough reflex, which could act as a protective mechanism to minimise aspiration. A prophylactic effect of taking acid suppressive medications is that it may supress gastric reflux thereby reducing the risk of potential aspiration of gastric contents into the lungs. Conversely taking acid

suppressive medications can alter gastric pH thereby allowing bacteria to multiply which if aspirated could potentially lead to development of pneumonia. Within the hospital, these medications are not used prophylactically but may be used during the acute phase to treat other conditions. Some patients are already on these medications preadmission, which may have a prophylactic effect or be a confounding factor.

4.1.9 Reflexivity and insider-outsider perspectives

Reflexivity emphasises the importance of one's own cultural, political, social, linguistic and ideological origins and voice (Patton, 2002) and acknowledges their potential to shape the research process (Mason, 2009). A potential bias in this project relates to the insider-outsider perspective of being a researcher collecting data in a setting where they were primarily perceived as a clinician and the blurring of boundaries when potential professional and ethical considerations needed to be taken during data collection.

The researcher anticipated the potential for ethical dilemmas to arise during data collection. They discussed them with their supervisors so that, if they arose, they could be alert to them and make reflected decisions. The researcher kept a reflective log of their observations, experiences, and initial interpretations and sought verification about how they approached each situation as required. One example was a patient who was NBM with a percutaneous endoscopic gastrostomy (PEG), but who was eating and drinking small amounts prior to admission. The patient had not been referred to SLT, and the ward staff appeared unaware of the patient previously having oral intake alongside their PEG. Being entirely NBM had the potential to impact on the patient's quality of life during admission. This sensitive issue identified with the researcher emotionally and clinically and they alerted their SLT colleagues to the patient's admission and to request a swallow assessment. This example could have potentially impacted on the timeliness of the patient's swallow being assessed and the result of the clinical audit. However, in this example the patient had already breached the 72-hour target for a specialist swallow assessment, therefore intervention by the

researcher did not impact on the reported performance versus the SSNAP standards.

Another example of blurred boundaries was when the researcher was on the hyper acute stroke unit in their researcher capacity outside of normal SLT working hours. A nurse asked for advice as the ambulance crew were waiting to return the patient to their place of residence. The interaction and review of the patient medical record highlighted that the dysphagia screener had not followed the protocol. They had not assessed the patient with the recommended diet consistencies, there were inconsistencies in the patient record regarding the outcome of the screen and the patient had not been referred to the SLT team following the screen. The researcher reverted to their professional role. They established what diet consistency the patient had been managing safely and asked the nurse to handover this information to the patient's residential home. The researcher liaised with the SLT team about arranging a community review.

Another example of when the researcher's professional responsibilities made them intervene was when they became aware of the potential discrepancies with what was being recorded on the SNAPP database. They discussed this with the Project Lead and agreed to meet with the person responsible for inputting the SSNAP data and the SLT Stroke Team Leader, to highlight the differences and possible reasons, so that this could be addressed before the end of the clinical audit.

A further example, which had potential to impact on the results, was that ward staff might have become aware that the researcher was conducting a clinical audit about the timeliness of dysphagia screening and swallow assessments and so may have behaved differently as a consequence.

4.1.10 Generalisability

This clinical audit has provided a perspective from one hospital of acute dysphagia assessment and management, which will have implications for

generalisability to other hospitals registered on the SSNAP database. However by taking a deeper dive beneath the SSNAP key indicators it has identified potential for variations in processes and practice and will inform questions for the national survey. Examples of possible variations in practice include: admission pathways, staff groups trained to do dysphagia screens and specialist swallow assessments, 7 day working for SLTs, use of instrumental swallow assessments, oral care regimes and NGT feeding protocols.

The case note review also highlighted the potential for differences in the use of management strategies to reduce risk of pneumonia reported in the literature compared to local practice. Discussions with pharmacy identified that the use of ACE inhibitors was not used as a preventative measure. It also highlighted that in the case of prescription of acid suppressive medications these were used as prophylactic measure to reduce risk of ulceration in patients on aspirin rather than as preventative measure to prevent gastric reflux. The case note review also highlighted how some patients were already on some of these medications or antibiotics pre admission which raised the risk of potential confounding.

Another possible confounding factor which may impact on the generalisability of the results is the participation of hospital sites in clinical trials, which involve pharmacological interventions to prevent pneumonia such as PRECIOUS: PREvention of Complications to Improve OUtcome in elderly patients with acute Stroke. The hospital was a site for this randomized, open, phase III, clinical trial. During data collection for the case note review the sample was monitored for recruitment.

4.1.11 Dissemination of the results

The results of the Case Note Review have been written up and submitted as a report to the Clinical Effectiveness Unit. The results have been disseminated to the Project Team and SLT Stroke Team leader.

As part of the Action Plan as Project Lead, the researcher met with the Band 7 SLTs responsible for dysphagia education in the Trust specifically for newly qualified nurses as part of the Preceptorship programme and dysphagia screening training. Findings relevant to both staff groups included being knowledgeable about the National Clinical Guideline for Stroke and the relevant SSNAP standards, being aware that patients are not necessarily directly admitted to a stroke bed, establishing what is 'normal' for a patient in terms of pre admission fluid and diet consistencies and if they have a previous history of swallowing problems, and knowing the National Clinical Guideline for Stroke relating to oral health. Specific findings relevant to dysphagia screeners included raising awareness that all patients should be screened within 4 hours of admission and that if a patient is transferred into their care who has been reported to have been eating and drinking since admission but who has no screen documentation, the dysphagia screening protocol should be followed. Educators were asked to emphasise the importance of staff adhering to the screening protocol, being flexible to requests to screen patients on another ward if needed, and to target recruitment to dysphagia training sessions to high admitting wards. Findings specifically relevant to newly qualified staff included being aware to act quickly if a patient was admitted with a possible stroke and in the first instance to identify the trained screener on the ward. If no one was available staff should bleep the Stroke Nurse to request the patient is screened or the Matron on Duty to identify an available screener.

The results have also been disseminated to the Matron and Nurse Director in charge of acute stroke care and presented at the Combine Community and Acute Care Group Integrated Geriatric and Stroke Medicine (IGSM) Audit Meeting and the Trust Clinical Effectiveness Committee.

4.1.12 Conclusion

The case note review highlighted the underperformance versus the National Guidelines for stroke patients to have a dysphagia screen within 4 hours of admission and those identified at risk of dysphagia to have a SLT swallow

assessment within 72 hours of admission. This information is already collected as part of the SSNAP audit but has provided further information for why these targets are not being met. Risks of patients not being screened for dysphagia have been identified and an action plan has been put in place to reduce the risk to an acceptable level.

The case note review identified discrepancies in the reporting of the number of patients who have a SLT swallow assessment within 72 hours of admission and the number of patients who are prescribed antibiotics for a newly acquired pneumonia compared to what is recorded on the SSNAP database for the National SSNAP Audit. This has implications for performance targets but also the accuracy of the SSNAP database.

The case note review has also highlighted how documentation such as the Stroke Nurse Specialist/HASU Nurse Assessment and the Dysphagia Screening Protocol is not always complete. One noticeable omission on the Stroke Nurse Specialist/HASU Nurse Assessment Stroke was the prescription of mouth care for NBM patients. This raises the question of the effectiveness of the existing method for prescribing mouth care and how much priority is given to mouth care for NBM patients, some of whom are unable to undertake their own oral hygiene. The clinical audit also found patients can attend X-Ray multiple times during the first 7 days to confirm the siting of their NGT, which can lead to delays in NG feeding.

By gaining a better understanding of dysphagia assessment and clinical processes and medical interventions associated with acute stroke patients with dysphagia, this clinical audit has added to the information reported by SSNAP. It has highlighted reasons for discrepancies between actual practice and standards and made recommendations for what action needs to be taken to improve performance locally. It has also improved awareness of potential variations in practice that may contribute to risk of SAP that will be further explored in the national survey.

4.2 Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study

Eltringham, S. A., Smith, C. J., Pownall, S., Sage, K. and Bray, B. (2019a) 'Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study.' *Geriatrics (Basel)*, 4(4), Oct 25, 2019/11/17

4.2.1 Introduction

Stroke-associated pneumonia (SAP) is defined as a spectrum of lower respiratory infections within the first 7 days of stroke onset (Smith et al., 2015). It is one of the most frequent post-stroke infections affecting 14% of patients (Kishore et al., 2015) and is associated with a three-fold increase in hospital mortality (Katzan et al., 2003), prolonged hospital stay and poor functional outcomes (Finlayson et al., 2011). The pathophysiology of SAP is multifactorial. Stroke induced immunosuppression, aspiration of oropharyngeal secretions and stomach contents, related to impaired consciousness and dysphagia increase vulnerability to SAP in the acute phase (Hannawi et al., 2013).

Dysphagia occurs in 37–78% of stroke patients and increases risk of pneumonia 11-fold in patients with confirmed aspiration (Martino et al., 2005). In the United Kingdom (UK), national guidelines (ISWP, 2016b) recommend people with acute stroke have their swallow screened within 4 h of hospital admission by a specifically trained healthcare professional and, if dysphagia is suspected, the person should have a specialist swallow assessment by a speech and language therapist (SLT) within 72 h of admission (Supplementary Table S1: Summary of Royal College of Physicians (RCP) Clinical Guideline for Stroke). There is increasing evidence that early dysphagia screening is associated with reduced odds of SAP (Al-Khaled et al., 2016; Bray et al., 2017; Palli et al., 2017) and that delays in SLT assessment increase pneumonia incidence by 1% per day of delay (Bray et al., 2017).

The type of dysphagia screening protocol (DSP) used varies widely and there is limited information about the components of the specialist swallow assessment (Eltringham et al., 2018). Screening protocols can vary from informal screens to validated protocols that assess with water only (Martino et al., 2009; Leder and Suiter, 2014) and stepwise screens that provide separate evaluations for non-fluids and fluids (Trapl et al., 2007). The RCP Clinical Guideline for Stroke state that there is good evidence that a multi-item DSP that includes at least a water test of 10 teaspoons and a lingual motor test is more accurate than screening protocols with a single item, but do not recommend a standardised screen. Typically, a swallow assessment by a SLT comprises a cranial nerve examination, trials of different fluids and diet textures and compensatory strategies. Those suspected of risk of aspiration should be assessed for instrumental examination using techniques such as videofluoroscopic swallowing examination (VFSE) or fibreoptic endoscopic evaluation of swallowing (FEES). These assessments provide direct imaging for assessment of the swallowing physiology and help to predict outcomes and treatment planning.

A range of medical interventions and clinical processes may also be associated with the risk of SAP in patients with dysphagia. There is emerging evidence for the use of preventative measures such as screening for stroke-induced immunosuppression and dysphagia, for identifying patients at high risk for SAP (Hoffmann et al., 2017). Further studies are needed to test this and screening for oral aerobic Gram-negative bacteria (Gosney et al., 2006) as well as the need to evaluate if treatment with proton pump inhibitors (Arai et al., 2017) and nasogastric tubes (NGT) (Brogan et al., 2014; Kalra et al., 2016; Langdon et al., 2009) are associated with SAP in patients with dysphagia.

This study forms part of an over-arching series of studies aiming to explore whether variation in assessment and management of dysphagia in acute stroke affects the development of SAP. Interviews with staff responsible for dysphagia screening, assessment and or clinical management of stroke patients were undertaken as part of a mixed methods research design to

inform the development of a national survey of hospitals registered in the Sentinel Stroke National Audit Programme (SSNAP) database (www.strokeaudit.org). Statistical analysis of the survey responses with the database will highlight barriers and facilitators for reducing SAP. The aim of the interview study was to explore beyond the 4-h and 72-h audit criteria for screening and assessing patients for dysphagia to give a more rounded picture of care beyond the SSNAP performance indicators.

4.2.2 Methods

The study sits within a realist positivist orientated paradigm. Interviews were chosen for their ability to provide a rich source of information about practice across different hospitals and subjects' opinions and experience of these practices. The interviews were semi structured which enabled the researcher to ask a series of questions and follow-up any additional or complementary issues. Questions were as open as possible in order to avoid closed 'yes/no' responses and questioning techniques were used to encourage participants to communicate their attitudes and beliefs. Hospital sites for participant recruitment were selected from five regions in England (Yorkshire and The Humber; East Midlands; Manchester, Lancashire and South Cumbria, and London). Regions were selected based on proximity to the host institution and representative of centralised versus non-centralised models of acute stroke care. Hospital sites were identified from the SSNAP database based on size (comparable to the host institution) and maximum variation against SSNAP key performance indicators (a) patients given a swallow screen within 4 h (b) patients given a formal swallow assessment within 72 h and (c) prevalence of SAP. The SSNAP data periods analysed were 04/15–11/16 and sites were selected based on the regional composition of the Strategic Clinical Networks between 04/15–03/16. A local collaborator was identified at the non-host sites to identify potential participants. The interviewer worked in one of the hospital sites where three staff interviews took place and knew the participants.

A purposive sampling strategy was used to recruit staff from different professions who work in hyper-acute and acute stroke care and who were involved in dysphagia screening, assessment and management of patients with dysphagia. Staff typically involved in dysphagia screening and assessment, and clinical management in hyper acute care include stroke nurse specialists, nurses trained in dysphagia screening, SLTs, ward sisters and doctors. The target sample for the interviews was fifteen participants. The sample size for the interviews reflected that staff would be interviewed from five different hospital sites and enabled representation from different staff groups. Data saturation was reached when no additional or new data was being generated. Service users were involved in the design of the research and participant materials.

Ethics approval was provided by London-Bromley Research Ethics Committee (REC Ref 18/LO/0096) and the primary authors' academic institution REC (Ethic Review ID ER5599201). Information about the study was disseminated electronically to potential participants. Those who agreed to participate were invited to an interview and written consent was obtained before participation.

Interviews were conducted between 27 April 2018–14 September 2018 by the primary author and recorded using an Olympus WS-853 digital voice recorder. The topic guide was developed based on themes emerging from the literature (Eltringham et al., 2018; Eltringham et al., 2020). Questions were grouped by professional relevance. The topic guide allowed for follow-up questions to accommodate new insights emerging (Table S2: Topic Guide). The primary author transcribed each audio file into a Microsoft Word document. Transcriptions and any potential sources of identification were anonymised.

Data were thematically analysed using a six-stage process (Braun and Clarke, 2006). This began with the primary author immersing herself in the interview data. Conducting the interviews allowed some prior knowledge of the data and some preliminary analytic thoughts. The transcription of the

data from the audio files informed the early stages of the analysis. Checking the accuracy of transcription against the audio recordings enabled familiarising with the data and some initial interpretations were noted. The transcripts were read and re-read and segments of text were identified and coded manually. The topic guide and sequence of questions provided an initial basis for coding and generating themes. As part of the iterative process, the themes were reviewed by the co-authors and categorised into cross cutting meta-themes. These meta-themes were then defined and named.

Several techniques were used to ensure rigour. During the interview, the primary author asked probing and interpreting questions to pursue an answer and to clarify what was said. To understand the implicit meaning of what was said, the interviewer sent it back to the interviewee to obtain an immediate confirmation of the interpretation (Kvale, 2007). The primary author kept a reflective log and sought to confront and challenge any assumptions by embracing alternative or counter information. The research team provided peer validation of the interview themes. The Standards for Reporting Qualitative Research (SRQR) (O'Brien et al., 2014) were used to assist with transparency of reporting and to facilitate judgments about the trustworthiness, relevance and transferability of the research findings.

4.2.3 Results

4.2.3.1 Sample

Fifteen staff were recruited across five hospitals. Participants included nurses (n = 6), doctors (n = 4) and SLTs (n = 5), with a range of years of experience (4.5–27 years; mean 14.23, standard deviation 6.36, standard error 1.64). Five participants were trained to screen patients for dysphagia and six to complete a comprehensive swallow assessment (Table S3: Participant Characteristics). Individual face-to-face interviews were conducted with the exception of one interview, which involved two people from the same hospital from different professional groups. The interviewer

was flexible to a request that the two participants were interviewed together to accommodate their busy work schedules.

4.2.3.2 Themes

Three meta themes were generated which cut across acute phase stroke care (Table 4.2). These themes and sub themes are set out and illustrated with anonymised quotations.

Table 4.2 Themes and sub themes.

Themes	Sub themes
Delay	Patient, staff and service factors that contribute to delay in dysphagia screening, SLT swallow assessment and NGT feeding
Lack of standardisation	DSP, SLT swallow assessment, oral care, NGT insertion and confirmation of positioning
Variability in resources	Resources to assess and manage swallowing, medical interventions, care processes

SLT – Speech and Language Therapist, NGT – Nasogastric Tube, DSPs – Dysphagia Screening Protocols

4.2.3.2.1 Delay

This theme refers to delays in dysphagia screening within 4 h of admission, comprehensive assessment by a SLT within 72 h of admission and NGT use in patients deemed unsafe to swallow. The theme is subdivided into three sub themes: patient, staff and service factors that contribute to delays.

4.2.3.2.1.1 Patient Factors

Delays in dysphagia screening and assessment by a SLT included: (a) Patients who were not sufficiently alert for screening and assessment; (b) patients who were medically unwell; (c) patients with subtle swallowing difficulties that were not initially identified and (d) stroke patients who had been misdiagnosed.

'Number 1 the reason I can see for delays is the patient's inappropriateness to complete the screen…they're not alert enough or not awake enough or medically not able to have to have it'. (H1P2)

'Delays are obviously due to the fact that subtle swallowing difficulties… are not really picked up the junior doctors or senior doctors or even nursing staff'. (H4P1)

'If it's a stroke but atypical stroke presentation…patient can go somewhere else and basically the screen will not be done because there's no risk of any swallowing problems. The patient might be fed and then realised that patient is coughing or having difficulty 24–48 h later CT (Computerised tomography) is done then realising there is a stroke'. (H2P2)

4.2.3.2.1.2 Staff Factors

Delays in dysphagia screening included: (a) Lack of trained staff to screen patients in the emergency department (ED), (b) time management, (c) lack of awareness of the national guidelines (ISWP, 2016b), (d) pressure on the admitting stroke nurse to carry out the screen and (e) multiple admissions at the same time where the screen may be deprioritised if another patient required medical intervention;

'They don't have any trained nurses down there [Emergency Department] it's normally the [stroke] nurse that does it so only one person'. (H5P4)

'It depends on the level of sort of competence in managing the time and how quick and efficient they are as well'. (H2P1)

'If they've come from a different ward and that ward may not be as knowledgeable as our staff regarding how quickly they should be screened'. (H4P4)

'The typical scenario might be 3 or 4 patients arrive in ED (Emergency Department) at any one time and then obviously the emphasis would be very much on trying to restore brain function so where there can be an intervention early and that can take priority over a swallow screen on the initial patient you were seeing'. (H3P1)

Barriers for the 4-h screening target arose when staff assumed someone else had completed the dysphagia screen, not having a designated person responsible for screening patients and lack of monitoring and documentation about whether the screens had been done;

'I suppose I'm still a bit unclear about whose responsibility it is. I know that several people do the swallow screen but I'm just not sure that it's one person's role particularly. And I don't really know who is going around monitoring when swallow screens are happening'. (H1P3)

To help improve monitoring and documentation when a patient had been screened, one participant felt it would be helpful if all patients, even those who had passed the screen and were eating and drinking normally, had a notice placed above the patient's bed to show that the patient had been screened and what the outcome of the screen was.

'So maybe using those above the bed forms so even if they've passed their swallow assessment…perhaps putting a form up to say normal diet so we all know the swallow assessment has been done'. (H1P3)

Reasons for delays for patients receiving a SLT assessment included: (a) lack of 7 day working by SLTs, (b) insufficient resources during periods of annual leave, (c) receiving late referrals in the working day, (d) documentation and (e) delays in onward referral following completion of the dysphagia screen.

'7 day working…so there's always going to be day where there's no screeners where's no assessments to take place'. (H2P3)

'Staffing that is our main reason for us not being able to see the patient if we've got 2 people on leave'. (H2P1)

'Sometimes they forget to do follow the correct admin procedures'. (H2P1)

'Sometimes they forget to let us know so they'll do the screen put them on something'. (H2P1)

4.2.3.2.1.3 Service Factors

The way patients were admitted to a specialist stroke bed had the potential to impact on the timing of the dysphagia screen and SLT swallow assessment. In most hospitals, patients were admitted via the emergency department and were then moved to the hyper acute stroke unit (HASU). In one hospital, the HASU was located in a different hospital to the ED and there were no staff trained to screen patients who self-presented to emergency services. Patients who were identified as stroke were transferred to the neurology admissions unit /HASU by ambulance.

Variation in patient pathways had the potential to contribute to delays in dysphagia screening. In one hospital, for patients who were not admitted via the ambulance service as suspected stroke, there was a pathway for ED staff to decide whether or not to request a stroke doctor's opinion. Because of the busy ED environment, patients might not be seen for up to 6 h.

‘Because it’s so busy sometimes they don’t get seen by a doctor for 4 5 or 6 hours so that has an impact on getting the screen quickly’. (H3P4)

In another hospital, patients were admitted under different stroke streams. The stream could impact how quickly a patient would have their dysphagia screen. Patients admitted under the thrombolysis stream and who were suitable for thrombolysis would have their dysphagia screen done as part of the initial stroke assessments in ED.

‘They know they are not to leave A&E (Accident and Emergency) until they’ve swallow screened them so that tends to hit our four-hour window’. (H5P2)

The second stream was for patients who had breached the time window for thrombolysis. These patients would have to wait until a stroke doctor went to ED to assess them.

‘They won’t tell the stroke nurse about them until they’ve assessed them and accepted them under stroke which can often be pushing the four hour period and that’s when we would have issues with compliance’. (H5P2)

The third stream was for a small percentage of patients directly admitted to the HASU. In this stream, the stroke nurse would screen the patient on the ward.

The manner in which patients were referred to the HASU could also impact on the arrival time to a stroke bed and timing of the dysphagia screen. Patients could be referred via: general practitioners, walk in centres, transient ischaemic attack (TIA) clinics, ophthalmology clinics, local district general hospitals, self-presenters (‘people who know the services here and perhaps been here before’(H1P1)) and from another ward in the same hospital. Participants described the potential for delay:

'If they were in this hospital then they [the ward] would probably ring us and we would try and go down if we could. If they were in another hospital it would be reliant on whoever they've got to screen or assess but I would be doubtful whether it would be done within the four-hour time frame'. (H1P1)

Participants described a prioritisation and hierarchy of tests and investigations when patients are admitted which had the potential to impact on the timing of the dysphagia screen. There was a sense of urgency to complete the initial stroke assessments to confirm the diagnosis of stroke before the dysphagia screen. If the patient was considered for thrombolysis or thrombectomy, the dysphagia screen might be de-prioritised:

'I guess the swallow screen wouldn't be forgotten but might be, wouldn't be the first thing in the minds of the doctors and nurses'. (H1P3)

Delays associated with the commencement of non-oral feeding related to confirmation of the position of the NGT. In one hospital, the position of the NGT needed to be confirmed by a radiologist. In another hospital, reduced staffing over-night had implications for confirmation of positioning and delays in the patient receiving nutrition via the NGT.

'It's a bit different at night time because there's not many radiographers around so sometimes can take a bit longer to get that done' (H3P4)

Attending X-ray and repeated chest X-rays was felt to be negative for the patient for a variety of reasons. These included risk of exposure to infection while being off the ward, not being cared for by staff experienced in stroke, delays in the administration of medications and missing therapy sessions while the patient was having the investigation. There were also potential resource implications both in terms of staffing and the cost of repeated X-Ray.

'I actually really don't like my patients going down for X-Rays they end up going to a different part of the hospital where they pick up infection they don't

get the standard of care we would expect on the stroke unit and sometimes they miss out on a therapy session…just for the purpose of the X-ray and it's not necessarily the best approach'. (H3P1)

'It's not a good thing that the patient's having to frequently go off the ward for Chest X-Rays repeatedly because it delays feeding it delays administration of medications so it could have a negative effect on the patient and the resource issue'. (H1P3)

4.2.3.2.2 Lack of Standardisation

This theme refers to the lack of standardisation between hospitals related to protocols and policies. The theme is subdivided into four sub themes: dysphagia screening protocols, SLT swallow assessments, oral care and NGT insertion.

4.2.3.2.2.1 Dysphagia Screening Protocols (DSPs)

There was a range of DSPs used in the different hospitals (Table S4: Type of Dysphagia Screening Protocol). All of the hospitals used locally developed dysphagia screens; none used a standardised screen. Every DSP involved a pre-screen check/risk assessment to check that it was appropriate to screen the patient and an oral examination before starting with oral intake. The consistencies of fluids and types of diet used varied. Fluids and non-fluids ranged from water only, fluids only including water and thickened fluids and water and diet of varying consistencies. In every DSP, the sequence began with water. In one DSP, the screen was subdivided into a basic and advanced screen. The basic screen included water and regular easy to chew diet. If the patient failed the basic screen, a member of staff trained to administer the advanced screen would assess with thickened fluids and a semi-solid diet. One interviewee, a SLT clinical lead, identified a need for more standardisation.

‘I can’t understand why we’ve got so many different screens so much variance around the country I just think is absolutely crazy as a profession’. (H4P4)

4.2.3.2.2.2 SLT Swallow Assessment

None of the hospitals used a standardised assessment. SLTs applied their clinical reasoning to tailor their swallow assessment based on their knowledge, experience and observation. Typical components of the assessment included: a case history, checking the patient’s baseline recommendations, liaising with nursing staff to check if assessment was appropriate, an oro-motor assessment involving cranial nerve function and an assessment of fluid and diet of varying consistencies. There was variation in the consistency of diet and fluids that the SLT might assess swallow safety.

‘It’s been a long time ago that we devised it …we all devised our own when we were training’. ‘So, it’s something that’s engrained at this stage’. (H1P1)

4.2.3.2.2.3 Oral Care

There was variation in the approach to oral care. One hospital had a published oral care policy and in another hospital a policy was in the process of being written. In one interview where two participants from the same hospital were interviewed together, there was initially an inconsistency in their understanding about whether the hospital had an oral care policy. Both participants subsequently clarified it:

‘I don’t think there’s a formal policy there no written policy’ (H2P3) ‘no there’s no written policy’. (H2P2)

In the hospitals where there was no oral care policy, best nursing care was used as the policy standard. This varied from checking every 2 h, to a minimum of 4 hourly mouth care and twice-daily teeth brushing for nil by

mouth (NBM) patients. In one hospital there was a drive to standardise practice because of variance across the Trust.

'The practice educator forum have asked for a…report to be submitted for each of the individual areas… because it seems like everyone is doing their own thing either doing it differently or repeating what other people are doing which probably both aren't particularly appropriate'. (H5P2)

4.2.3.2.2.4 NGT Insertion

There was a general consensus across hospitals about the number of times to attempt to reinsert an NGT.

'So, the policy is just been updated…to say maximum of 3 NG (Nasogastric) tubes with a 24-hour period'. (H5P2)

One participant stated, '*There is no set number*'. They took a *'holistic approach'* which was to try and *'work out what the problem is and try and correct that before having another* go' (H3P1). The same participant questioned if enteral feeding was always appropriate.

'It's very easy to get stuck into a pathway when treating somebody who's maybe a modified Rankin score of 5 at baseline who's naturally at the end of their life'. (H3P1)

It was felt that confirmation of NGT position by chest X-ray (CXR) *'it's a bit more frequent than we would like' (H3P1)* and frequency varied by ward and the experience of staff on duty. As a consequence of two serious incidents in one hospital, there had been a recent change in that hospital's NGT guidelines, which had resulted in an increased number of patients, being referred to CXR.

One participant compared hospital practice with the community:

'So, in our community hospitals they are perfectly able to manage NGTs (Nasogastric Tubes) without radiology most of the time they don't need it so there is a standard of care there, what's the difference probably more senior nursing staff and a more holistic approach that maybe we need to find'. (H3P1)

4.2.3.2.3 Variability in Resources

This theme refers to resources and is subdivided into three sub themes: resources to assess patients swallowing, types of medical interventions and care processes.

4.2.3.2.3.1 Resources to Assess Patients Swallowing

Types of instrumental swallow assessments included videofluoroscopic swallowing examination (VFSE) and fibreoptic endoscopic evaluation of swallowing (FEES). There was variation in accessibility and waiting times for these investigations. VFSE was more widely available than FEES but was not undertaken within the first 72 h of admission; 'possibly within the first week towards the end of the week but not within the first three days' (H3P1). Difficulty accessing FEES were: (a) Availability of staff competent to use the equipment, (b) problems with the equipment or (c) no equipment. Staff attitudes were identified as a barrier to FEES utilisation.

'Speech therapists on the stroke unit aren't thinking about FEES (Fibreoptic Endoscopic Evaluation of Swallowing)'. (H5P4)

There was variation between hospitals providing a weekend SLT service and staff competencies to assess and manage patients with dysphagia. One hospital trained stroke nurses to complete specialist swallow assessments, which, in all the other hospitals, were carried out by SLTs. In another hospital, some nurses were trained to be competent to complete a basic screen with water only while others were trained to complete an advanced screen.

4.2.3.2.3.2 Medical Interventions

Medical interventions included prophylactic measures such as medication use and NG tubes. Nasal bridles were not in use in all hospitals. In one hospital, there had been resistance by nutrition nurses to use of nasal bridles because of the risk of complications such as substantial trauma to the nasal septum. However, this was under review.

Pharmacological interventions such as acid suppressive medications, oral gel for the treatment of bacteria in the digestive tract, antibiotics and antiemetics were not used prophylactically to reduce the risk of patients developing stroke-associated pneumonia. A reason given by one participant was the lack of *'randomised evidence base to guide our decision making so we would not use prophylactic antibiotics or anything like that'(H4P1).*

4.2.3.2.3.3 Care Processes

Staff resources had the potential to impact on patients receiving the SLT recommended level of supervision at mealtimes, and one participant identified a disparity in knowledge between healthcare assistants who assist patients to eat and drink and qualified nursing staff:

'Potentially a lot of patients with swallowing impairments are fed by healthcare assistants who have had training but not perhaps the background knowledge of anatomy and physiology to the same extent as qualified nurses have'. (H5P2)

There was also variation in resources to support the safe positioning of patients who were enteral and orally fed:

'I think what the big thing we noticed at lunchtime everything is great, at breakfast time things were awful patients weren't able to sit out of bed, when they're in bed they weren't positioned upright necessarily'. (H4P4)

There was a lack of access to professional oral care. One hospital had an oral care nurse however *'access to her isn't very easy' (H2P3)* due to the nurse working part time across the Trust. Specialist oral care products such as single use oral care packs, which included mouthwash and a suction toothbrush, were being trialled in some hospitals.

4.2.4 Discussion

This research highlights variances in dysphagia screening, assessment and management in stroke services within the UK. These variances have the potential to impact on quality of care and patient safety because of increased risk of pneumonia, poor oral hygiene, malnutrition and dehydration. This was particularly evident in the use of different, locally developed dysphagia screens in each of the hospitals, over the use of a standardised assessment such as the Gugging Swallowing Screen (Trapl et al., 2007). Lack of standardisation extended to oral care, with only one of the five hospitals having a formal oral care protocol. In the hospital where a formal protocol was in place, staff believed that it had reduced the number of clinical incidents relating to poor oral hygiene. Since 2010, there has been a centralisation of acute stroke care services in the UK so that patients are taken directly to designated specialist HASUs rather than to the nearest hospital. This has resulted in a larger proportion of patients being treated in hyper acute units with organised care (Morris et al., 2019). The further reconfiguration of stroke services to a more centralised 'hub and spoke' system has potential to improve the standardisation of protocols used to screen, assess and manage patients with dysphagia in acute stroke.

Delays in dysphagia screening and specialist swallow assessment are known to be associated with increased risk of stroke-associated pneumonia (Bray et al., 2017). Timely assessment is an example of how better care can lead to better outcomes for patients but also be cost saving (SSNAP, 2019). The current study identified a range of staff and service factors, which contribute to these delays. Variations in admission route and clinical

pathways all had implications for how quickly a patient would be screened by a trained professional, which then impacted on onward referral to SLT for a specialist assessment. Barriers to early dysphagia screening included lack of resources to support stroke nurses to screen patients and lack of ownership and responsibility for undertaking the screening and failure to check that patients had been screened. Lack of SLT 7-day working was identified as the main reason for delays in specialist assessment and patient's remaining NBM. To avoid this delay, two hospitals' dysphagia screening protocols involved screening patients with modified fluids and one hospital had trained stroke nurses to complete specialist swallow assessments in the same way as SLTs.

Having access to instrumental investigations such as VFSE and FEES to assess patients with dysphagia impacts on healthcare professionals being able to predict outcomes and treatment planning. The findings from this study suggest FEES is currently under-utilised in acute phase stroke because of lack of access to the equipment, untrained staff and staff attitudes. Similarly, nasal bridles were not used in all hospitals, despite national guidelines, which recommend patients should be assessed for a bridle NGT if their NGT needs frequent replacement. In a small scale multi centre randomised control trial of 104 patients, patients who had their NGTs secured using a nasal bridle received a higher proportion of nutrition and hydration compared to controls who had their NGT secured using standard practice (Beavan et al., 2010). Lack of uniformity in the use of nasal bridles had the potential to impact on patient care for patients transferred between hospitals.

Lack of standardisation is not unique to treatment of dysphagia in acute stroke. Dysphagia occurs as a consequence of different medical conditions and people are cared for in a range of health and social care settings. Dysphagia has been the subject of national patient safety alerts (PSA) in England (Ilott et al., 2016). Recently NHS England published a PSA about resources to support safer modification of food and drink for people with dysphagia (PSA, 2018). Seven patient safety incidents were reported where

imprecise terminology had caused significant harm. The Care Quality Commission, the independent regulator of health and social care in England, have also published a 'Learning from Safety Incidents' about caring for people at risk of choking. The Commission state that people should be assessed by a skilled and competent health professional and each person's care plan should be tailored to individual need (CQC, 2018).

Identifying variances in practice and linking this to the national stroke audit can help to understand what are the facilitators and barriers to reducing risk of stroke-associated pneumonia. The wider implications of this research will be to inform national and international clinical guidelines and improve quality of patient care and outcomes. Staff awareness of assessment and management of swallowing problems as essential to patient safety needs to be continually raised, as well as their increased understanding of best practice for assessment and management of dysphagia during the critical 72-h period post admission for stroke patients.

Potential limitations of the study include; first, that the primary author is a SLT and works in one of the hospital sites where three staff interviews took place and has worked with these staff as part of a multidisciplinary team. The main author also supported one of these participants in her clinical role with their dysphagia screening training. The interview structure was the same as the one used with unfamiliar participants. However, there may have been a risk of bias in that those participants known to the interviewer may have felt more of an obligation to take part in the study and then to provide particular responses based on what they thought the interviewer might want to hear. There was also potential for participants to perceive questions about practice as being critical, despite reassurances that the study's intention was not to judge or assess their practice. Second, this was a UK regional study and its findings may not be transferable to other countries or be representative of overall UK care. Third, the sample size was small and may not therefore have been able to capture all possible opinions from the wider UK acute stroke community, although the composition of the sample was able to provide a range of clinical perspectives. The amount of variation and new

areas during the interview data collection, levelled off, with no new perspectives or explanations coming from the data, which suggests saturation was reached. The triangulation within the concurrent mixed methodology also ensures rigour of the research.

4.2.5 Conclusions

This research identified a range of patient, staff and service factors that have the potential to impact on stroke patients who are screened and assessed for dysphagia. The findings add support to what is known about the lack of standardisation of dysphagia screening protocols in the UK and highlights further variation in practice relating to resources and care processes in acute stroke care across hospitals. Highlighting these variations will help improve understanding of what factors impact on the development of stroke-associated pneumonia and improve patient care and outcomes.

The supplementary material is available in the Appendix D – Supplementary Material for the two interview studies (Page 299).

4.3 Patient and Public Involvement in the Patient and Carer Interview Study

This section expands on the methods of the published paper ‘Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers’, focuses upon the involvement of members of the Stroke Association’s ‘Stroke Voices in Research’ (SVR) Group in the interpretation and analysis of the patient and carer interview data, and the dissemination of the research findings.

4.3.1 Analysis and Interpretation of the data

Members were provided with accessible versions of the interviews and transcripts to listen to and read. They were invited to a half day focus group discussion about their interpretations. This 2-stage approach gave members the opportunity to make notes about what immediately struck them about the interviews based on their own interpretations before meeting as a group. The dynamics of the focus group gave the opportunity for shared discussion about the data, stimulated further discussion and development of the themes and identify new themes.

Preparation for the focus group involved working closely with the Panel's Coordinator to identify individual members training needs and support requirements to engage meaningfully in the analysis. The transcripts were made accessible according to individual need and included typed transcripts in large and easy to read font, with double spacing and an audible version, made with 'actors' reading the transcripts. A glossary of acronyms and terminology was provided, and members were able to contact the researcher if they had any questions during their involvement.

The focus group took place in an accessible venue, with accessible facilities. Members were invited to bring a carer to accompany them to the meeting. To help members who may need extra time in the morning and ease of travel, the meeting avoided peak travel times, starting mid-morning and ending mid-afternoon. Members were told they would be reimbursed for their travel and time. They were also able to choose to have their travel booked for them if more convenient and to avoid any delay in reimbursement.

Before the focus group started, members were shown a relaxation and rest room nearby where they could go if they wanted to leave the discussion and spend some time alone or needed some one-to-one time with a member of the research team. Throughout the meeting, members were provided with regular refreshments and comforts breaks and with lunch as a longer break in the middle. At the meeting, specific time was set aside to build rapport with

the team. Name cards were provided to help members remember each other's name and everyone was asked if they could introduce themselves. A breaking the ice activity was used at the beginning of the session.

To ensure safe, honest, and respectful communication, there were some ground rules for the discussion. These included being mindful that people may have different interpretations of the interviews and the need to listen to others and that what was shared was confidential as were the materials contained in the transcripts and so not to be discussed outside the meeting. The researcher facilitated the discussion by modeling open questions to encourage discussion. Members were asked to give examples from the interviews to support their opinions and consideration was given to ensure everyone's voice was heard.

4.3.2 Disseminating the findings

The SVR group were involved in the communication of the research findings to people affected by stroke and stroke health and social care professionals. A poster presentation about service user involvement in the analysis of qualitative research was made at the 2019 UK Stroke Forum in Telford (Eltringham et al., 2019c). The group were involved in the development the poster. They provided feedback on preliminary drafts which resulted in the poster focusing on the key information so that it was more visually impactful and would encourage attendees to stop and engage with presenter to find out more information.

4.4 Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers

Eltringham, S. A., Pownall, S., Bray, B., Smith, C. J., Piercy, L. and Sage, K. (2019b) 'Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers.' Geriatrics (Basel), 4(4), Dec 7, 2019/12/11

4.4.1 Introduction

The global burden of stroke is increasing (Gorelick, 2019). In Europe, the number of people with stroke is estimated to rise by 27% between 2017 and 2047, due to lower fatality rates and prevention strategies (Wafa et al., 2020). Stroke-associated pneumonia (SAP) is a frequent complication affecting 14% of stroke patients (Kishore et al., 2015), and is associated with increased mortality (Katzan et al., 2003), greater length of hospital stay and acute care costs (Ali et al., 2018), and dependency at discharge (Finlayson et al., 2011). Patients are susceptible to SAP in the first days after stroke due to a combination of stroke-induced immunosuppression and material such as oral-pharyngeal secretions or gastric contents entering the lungs (aspiration) as a consequence of reduced consciousness and difficulty swallowing (dysphagia) (Hannawi et al., 2013). Post-stroke dysphagia occurs in 37–78% of patients and increases risk of pneumonia ≥3-fold and 11-fold in patients with confirmed aspiration (Martino et al., 2005).

Early dysphagia screening and specialist assessment by a speech and language pathologist (SLP) is associated with reduced risk of developing SAP (Bray et al., 2017). In the United Kingdom, guidelines (ISWP, 2016b) recommend people with a stroke are screened for dysphagia within 4 h of admission to hospital and, if dysphagia is suspected, a comprehensive swallow assessment, usually carried out by a SLP, is undertaken within 72 h. A wide range of dysphagia screening protocols (DSPs) are used to screen people and there is limited information about what comprises a specialist swallow assessment (Eltringham et al., 2018). A range of medical

interventions and clinical processes may also be associated with risk of SAP in people with swallowing difficulties (Eltringham et al., 2020).

4.4.1.1 Aims of the Study

This study forms part of a series of studies (Eltringham et al., 2018; Eltringham et al., 2020; Eltringham et al.; 2019a) that aim to investigate how variation in assessment and management of dysphagia in acute stroke affects development of SAP. The aim of this interview study is to explore the experiences of people with swallowing difficulties following a stroke to give a more rounded picture of delivery of care and ensure that the perspectives of stroke survivors and their informal caregivers are included. We wanted to include the patient story of swallowing difficulties post-stroke as a way to better understand the patient experience of dysphagia assessment and management, as well as the views of the staff involved (Eltringham et al., 2019a; Wilson, 2019). Including the patient story has the potential to highlight variations in practice from the perspective of the persons affected, thereby providing a more inclusive understanding of service delivery. Informal caregivers can also provide another dimension and a contribution to better understanding of patient care as well as insight into their role. We wanted to extend beyond formal data collection against narrow performance indicators by interviewing people who had a swallow assessment during the first 72 h of admission into hospital, alongside other clinical processes and/or medical interventions that take place in the first few days post-stroke.

The study also wanted to actively involve stroke survivors not as research subjects but as research partners within the research process to help analyse the interview data and build the themes collaboratively with the academic research team. We wanted to involve people affected by stroke because of the unique insights they can bring thereby helping to ensure the relevance and quality of the research but also because it is a core democratic principle that people affected by research have a right to have a say in how publicly funded research is undertaken (Hayes et al., 2012).

4.4.2 Methods

4.4.2.1 Qualitative Approach and Research Paradigm

The interviews reflect the ontological assumption that reality is shaped by experience and the epistemological perspective that a subjective representation of this reality is being presented from the researchers' perception. Interviews were chosen for their ability to provide a rich source of information about people's experiences of having their swallowing assessed during the acute phase of stroke and their opinions and feelings associated with these experiences. A participatory methods approach involving a group of people affected by stroke in the data analysis embodies a process by which the analysis and interpretation of the data is not the sole responsibility of the researcher but a shared responsibility with the people themselves.

4.4.2.2 Researcher Characteristics and Reflexivity

The primary author is a SLP working in an acute hospital. There was the possibility that she may have had contact with the sample population whilst working in a clinical role. To avoid the risk of any researcher-practitioner conflict, the researcher did not recruit a patient or informal caregiver with whom she had any direct clinical contact. During an interview, there was also the potential for a participant to disclose something, which could present harm either to themselves or others. Participants were informed of the boundaries of confidentiality and as such, what could not be held as confidential (Allmark et al., 2009). Conducting the interviews meant that the researcher had some prior knowledge of the data and some initial analytic thoughts. The primary author kept a reflective log of initial interpretations and sought to challenge any assumptions by embracing alternative or counter information.

4.4.2.3 Environment

The context for the interviews was dependent on where the person was in the stroke pathway and their preferred setting. This included the acute stroke unit, the stroke rehabilitation unit or the person's home (Supplementary Material—Table S1). Participants were asked if they would like their informal caregiver to attend the interview to support them during the interview.

4.4.2.4 Sampling Strategy

Participants were identified from a convenience sample from a case note review from a single hospital. The sample included patients who had a dysphagia screen on admission and who went on to have a swallow assessment by a SLP or an equivalent trained professional. The sample size for the interviews was based on the objectives of the patient interviews in context of the overall research project (Baker and Edwards, 2012) and feedback from service users.

4.4.2.5 Ethical Approval

The research obtained ethics approval from London-Bromley Research Ethics Committee (REC Ref 18/LO/0096) and the primary authors' academic institution REC (Ethic Review ID ER5599201). Potential participants were approached and provided with information about the study. Those who agreed to participate were invited to an interview and written consent obtained before participation.

4.4.2.6 Data Collection Method and Instruments

Interviews were conducted between 17 April 2018–12 June 2018 by the primary author and digitally recorded using an Olympus WS-853 digital voice recorder. A topic guide was developed in response to a direct request from the patient and public involvement (PPI) group involved in the research study that service user perspectives be included. The guidelines for dysphagia

screening and assessment in acute stroke care (ISWP, 2016b) were used to help frame and sequence questions about what happened to an individual in the first few days post-stroke. The guide was exploratory and open questions were used, in order to elicit spontaneous descriptions of respondents' experiences. Visual materials such as calendars were used to help people recall when they had the stroke and the first few days following.

4.4.2.7 Units of Study

Face-to-face interviews were conducted with five people with stroke. The person with the stroke was the sole participant in three interviews and two involved the person and their informal caregiver. There was one informal caregiver only interview (Supplementary Material—Table S1). The time of the interview ranged between 8 and 100 days post-stroke onset.

4.4.2.8 Data Processing

The digital recording of each interview was uploaded to the primary author's academic institution Research Store and deleted from the recording device. The primary author transcribed each audio file and any potential sources of identification were made anonymous.

4.4.2.9 Data Analysis

There were three stages to the data analysis. The first stage involved the researcher and the academic research team. This began with the primary author familiarising herself with the interview data. The transcripts were read and reread and segments of text were identified, coded manually and categorised into themes. As part of the iterative process, the academic research team also reviewed the themes. The second stage of the analysis involved three members of the Stroke Association's 'Stroke Voices in Research' (SVR) panel. Members who had previously expressed an interest in being involved in research about swallowing were sent information about the study and scope of the involvement and invited to attend a half-day focus

group. Steps were taken to allow members to engage meaningfully in the analysis. This included tailoring support and resources to individual needs. Anonymised transcripts in audio and written formats and a glossary of terms were provided in advance of the meeting, and members were able to contact the primary author if they had any questions during the course of their involvement. At the focus group, the researcher facilitated members to discuss their interpretations of the interviews and identify segments of data as evidence. Together, they explored if any of the points raised cut across more than one interview and labelled and categorised the data. In addition, the group reviewed and validated the themes developed by the main author, independently identifying and labelling the same segments of data.
The final stage of the process was to triangulate the findings from the focus group with the research team analyses and define and name the themes.

4.4.2.10 Techniques to Enhance Trustworthiness

Several techniques were used to ensure the trustworthiness and credibility of the data analysis. During the interview, the primary author asked probing and interpreting questions (Kvale, 2007) to pursue an answer and to clarify what was said. The SVR panel and the research team provided peer validation of the interview themes. The Standards for Reporting Qualitative Research (SRQR) (O'Brien et al., 2014) was used for transparency of reporting. The Guidance for Reporting Involvement of Patients and the Public (GRIPP2) (Staniszewska et al., 2017) was used for the reporting of patient and public involvement (PPI) in the research.

4.4.3 Results

Six themes were identified. These included (1). Past-future experiences; (2). Understanding what is happening and adjustment to the stroke; (3). Impact of dysphagia; (4). Attitudes to care; (5). Communication by staff to the individuals affected by stroke; and (6). Procedural issues. The first four themes were developed by the researcher and validated by the SVR panel members. Where the SVR Panel enriched these themes is identified. The

fifth and sixth themes were new themes identified by the panel members and developed during the focus group. The themes are elaborated using quotations from original data to substantiate the analytic findings. The results also include matters identified by the SVR panel that the participants did not raise and which were relevant to their own experiences. This section is entitled 'The Unsaid'.

4.4.3.1 Past-Future Experiences

This theme describes how people's past-future experiences may influence a person's emotional response or understanding of procedures, medical interventions and concerns about risk of developing pneumonia. One participant had a choking episode, which resulted in a cardiac arrest call. Since his stroke, his informal caregiver had become aware of the recommended guidelines for people to remain nil by mouth (NBM) until screened for dysphagia. This new knowledge led her to reflect on what should have happened and the potential consequences;

"What I couldn't understand was is in all the leaflets I've got there it says they test you for your swallowing when you first go in, but you were never tested, were you?" (P35)

"Luckily he survived but if that domestic hadn't been there, who knows. (P35)

The same person required a percutaneous endoscopic gastrostomy (PEG), a procedure in which a flexible feeding tube is placed into the stomach, which allows nutrition and fluids to be put directly into the stomach bypassing the mouth and oesophagus. His caregiver's emotional response to this news had been shaped by their friends' experiences;

"Then they said he'd have to have the PEG (Percutaneous endoscopic gastrostomy), which was a bit upsetting for us because we knew three people who were PEG-fed and he's always said must be terrible to have to be fed like that and then it happened to him." (P35)

One participant's parents had both died of pneumonia and his expectation of developing pneumonia was influenced by his parents' experience. He was *"expecting repercussions" (P38)* as a consequence of his dysphagia. His informal caregiver stated, *"He was convinced"* he was going to develop pneumonia. One member of the SVR panel perceived that the person's concerns may have been a consequence of whoever had explained the risk of pneumonia to the participant, and that they "may have overdone it". The Panel member perceived the person to be still concerned about developing a chest infection.

4.4.3.2 Understanding What Is Happening and Adjustment

This theme refers to a person's understanding of what is happening at the onset of their symptoms, the adjustment to the effects of the stroke and the relationship with their informal caregiver. At the start of their symptoms, two participants were unsure about what was happening to them and described feelings of "denial" (P38, P151). Gradually, there was a realisation and acceptance that they were having a stroke. For one participant this was by listening to the use of the term 'stroke' by the ambulance crew on the way to the hospital;

"This is a stroke ambulance and we go to [hospital name]." "OK, stroke, we go the [hospital name] right." (P38)

For the other participant when he realised he couldn't swallow, he left the dinner table and went out into the garden where he became more self-aware as his symptoms evolved;

"I was panicking inside and then I started to feel my right side tickling, my right face here my arm my leg. Then I knew in my own heart what it were. I knew I were having some kind of stroke." (P151)

Members of the SVR panel likened these responses of 'denial' and 'acceptance' to the five stages of dying based on the works of Elizabeth

Kubler-Ross (Kubler-Ross, 1969), whose model has been applied to many stages of grief and loss. The panel perceived another participant displayed feelings of anger, which is another stage of grief, about his wife's rehabilitation. The panel felt the participant's emotional response was a consequence of unrealistic expectations of his wife's exercise tolerance, which was attributed to a lack of understanding due to poor communication by staff (see also Section 3.5—Communication to Patients).

Other examples of participants processing what had happened related to why recommended procedures had not been followed, the components of the SLP assessment and the rationale for the SLP swallowing recommendations.

"He's never actually had it tested when he first got in to see if he could swallow … I mean, at first, I didn't think anything about it, but reading all the bumf I've got I thought, well, he should have been tested for this straight away." (P35)

"But what surprises me was the first time they tried him with anything by mouth was sips of orange juice off the spoon and yet he can't have any liquids now." (P35)

It was the psychological effects of the stroke, which surprised another informal caregiver; *"What surprised me … is the mental effect it has on patients … because the mind seems to go and wander, could be over there somewhere or up there somewhere."* He spoke about the cognitive effect of the stroke on the person involved (P89), the adjustment and repair and how they were adapting to living with the long-term effects of stroke with the installation of equipment to help with daily living, when the participant returned home;

"We've got furniture in the house and a sling in, even though I don't like them." (P89)

The SVR Panel identified the participant's expression. "I'm frightened of them", (P89) when she was talking about the portable hoist equipment.

One participant (P133) described adjusting to the physical effects of the stroke. This included living with dizziness, feeling *"dry all the time"* and changes to her voice. The person felt *"frightened"* to go out, and described her voice like a *"darlek"*, which made her *"feel a bit down"*. One SVR member empathised that she could not drink tea anymore; *"I used to love a cup of tea and that but then I can't face one"*. Two participants used the term *"dark" (P89, P151)* to describe the impact of their stroke but had different attitudes. One participant stated, *"I call it my dark place where I don't like and don't want to be but I can't do anything about it" (P89).* The other stated, *"It's a dark time when you're laid there and your family's here and your family's upset and you think 'Why me?' but then you look around and you see other people that's a lot worse than you and it's a wake-up call, that to say 'Stop feeling sorry for yourself'" (P151)*. One member of the SVR panel associated the participant's *"dark time"* with being unable to eat. For two participants, as they regained their independence, they believed that their determination was the key to their recovery: *"I was determined I was going to walk I wasn't going to be messed about" (P155).*

Despite living with the ongoing effects of stroke, two participants described feeling they were lucky; *"I've been one of the lucky ones" (P151)* or their partner was lucky; *"So he was very lucky really and I think he was also lucky the fact that he didn't lose his speech and upper body. I mean he can use his hands, so he wasn't affected that way, but was just his walking and his swallow" (P35)*. One SVR panel member perceived this positive outlook to be a consequence of people measuring themselves against others, which resonated with his experience of a high rate of mortality of fellow patients in the first 48 h after his stroke.

4.4.3.3 Impact of Dysphagia

This theme describes the impact of having a swallowing difficulty on participating in social activities, participants' reactions to modified food and thickened drinks, and their swallowing ability and having a nasogastric tube (NGT) inserted. One informal caregiver spoke about the impact of having a PEG on being able to continue to socialise and participate in family celebrations, going out, and the loss of the enjoyment of eating;

"I thought, it's cruel really because what's happened to him because he really loves food and it's part of your social life: going out having a meal, having people to the house and going out with friends and family, isn't it?".(P35)

Members of the SVR panel also noted the importance of the stroke survivor going to the dining room for their meals. One participant's (P89) caregiver stated, *"I think is a good thing about being here, they take her to the dining room every meal"*. Two SVR members felt differently about the caregiver leaving at mealtimes rather than waiting for his wife to return from the dining room. One member perceived his behaviour as "a bit harsh", while the other member felt he was helping with his wife's rehabilitation. As well as the social participation of dining with others, the panel also identified participants' embarrassment of not being able to eat independently and eating in front of others.

Two participants had strong emotional reactions to being recommended thickened fluids and modified food by the SLP. They referred to the thickened drinks as *"horrible" (P133, P155)* and like *"sludge" (P133)*, and described the modified diet as *"slop" (P155).* The use of these emotive terms contrasted sharply with professional terminology used by the researcher, for example, pureed diet. To avoid drinking the thickened drinks, a family member would buy thick yoghurts as an alternative. Members of the SVR panel identified how the informal caregiver had bought more palatable alternatives. Based on their interpretation of the transcripts, they questioned if patients and caregivers were given adequate written advice on suitable

foods and the importance of maintaining a balanced nutritional diet. The SVR panel also perceived a "casualness" with regards to the thickening of patient's drinks and queried if staff responsible for thickening drinks were following the recommended guidelines. One participant stated the drink *"used to make it right thick" (P133)* and another, *"I don't know how much they had to put in, perhaps a spoonful of powder or something" (P155)*. Both participants demonstrated an understanding of what consistency and types of foods they were able to manage or should avoid; *"I can't eat anything with a crust on or anything like that, or else it gets stuck in my throat" (P133)* and *"I'm not on normal food now, but I'm on mashed-up food and … I can drink anything now" (P155)*. The perception of being able to eat *"normal"* food was associated with emotional and dysphagia recovery. Participants had a pragmatic response to their treatment and swallow recovery: *"There's a tunnel there and I'm getting to the end of it. Nothing will stop me" (P151).*

Informal caregivers were involved with the implementation of the SLP dysphagia recommendations. This included communicating the advice to the wider family, adherence to the advice and how that made them feel, providing assistance to eat and drink, and preparation of meals. One participant's (P38) caregiver acted as a conduit by updating the family on the SLP swallowing recommendations; *"I was keeping my family orientated 'cos all my family lives away"*. She described how she felt *"cruel"* for not giving her husband more to drink when he was on strict swallowing trials. The caregiver appeared to attribute responsibility for this to herself rather than to external factors such as professional advice: *"We sounded very cruel 'cos he kept saying, 'Can I have a drink?' … No, you can't you've had your five sips of water"*. This was made more difficult because her husband could not see any reason why he could not have any more.

Informal caregivers facilitated the implementation of the recommendations by assisting with mealtimes; *"And I used to feed you" (P89), and preparing meals "I made that [rhubarb and custard fool] for him" (P35)*, which adhered to the SLP consistencies. Members of the SVR panel highlighted the

potential burden on caregivers when their loved one returned home. Issues highlighted were the cessation of their own social activities, the additional care duties of preparing meals and assisting with PEG feeds, and the potential implications for their own emotional and physical wellbeing.

Three participants spoke about the discomfort of having the NGT inserted; *"not very comfortable at all" (P89), "I don't want that (Fibre endoscopic evaluation of swallowing), this (NGT) was bad enough" (P151)* and *"having it fitted was not very pleasant … having it there at times was quite painful because it would catch on different things" (P38)*. One SVR member who had experience of NGT insertion empathised with the discomfort. One caregiver felt the displacement and reinsertion of the NGT and confirmation of positioning had likely lengthened the time her husband (P38) had the NGT: *"We had to have the tubes fitted several times because it dislodged … so then you have to back down to the X-ray to make sure it's in the right place … so that's probably lengthened the time that he would because of it."* The importance of sustaining adequate nutrition and hydration was identified by the panel as important for the avoidance of worsening stroke symptoms.

4.4.3.4 Attitudes about Care

This theme refers to participants' attitude to treatment and awareness of staff roles. Participants praised the care they received and the attentiveness of the staff. An alternative interpretation from members of the SVR panel, of the attentiveness of the staff to the participant who choked, was that staff were trying to ameliorate the situation. Despite the incident, the informal caregiver *felt "everybody was there when it was needed" (P35).* Another caregiver had mixed feelings about the care and felt *"everything that has happened has gone too slow" (P89)*. The transition of one of the hospital stroke wards to a rehabilitation unit was felt to have impacted on the level of staffing on the stroke ward. This had direct consequences for personal care, which led to his wife feeling *"embarrassed all the time"* by her incontinence. They both spoke favorably about staff that spent time assisting at lunchtime.

Members of the SVR panel perceived a lack of recall on the part of many participants about when, where and what the swallow test was. One participant was aware of having lots of tests but did not always understand who people were and the SLP was sometimes confused with the occupational therapist. The same participant described how they (the person with stroke), the staff and their family were part of a team: *"It's a team, it gets you through it. It's not just yourself, it's a team. The hospital is a team. Your family is a team. When you've got that you'll get through it" (P151).* An informal caregiver described the sense of relief knowing that her husband (P38) was being looked after *"It's the relief of knowing that somebody's looking after who knows what they're doing is looking after him."*

4.4.3.5 Communication to Patients

This theme evolved from the analysis and interpretation of the data by individual members of the SVR panel and their collective discussion. The theme refers to examples of good and poor communication with patients and their informal caregivers about medical interventions, the risks of developing pneumonia, information about maintaining adequate nutrition and hydration, and the impact of stroke.

A perceived example of good communication about the impact of stroke and medical interventions included one participant's understanding of the impact of stroke on the swallowing process and the rationale for swallowing rehabilitation. The participant was having neuromuscular electrical stimulation swallowing therapy. The focus group agreed that the participant had a good understanding of his stroke and the rationale for the therapy.

An example of how communication about medical interventions was perceived as potentially lacking was the explanation to patients for the need for alternative long-term nutrition. One member of the SVR panel felt that staff should not be raising the matter of PEG with a patient until it had been established that feeding via a NGT was not going to work. A second example where communication about nutrition was felt to be potentially lacking was

information about the importance of nutrition for physiological recovery and how to maintain adequate nutrition and hydration (see also Section 3.3– Impact of dysphagia). SVR members perceived there to be a lack of information about nil by mouth status or if a patient was allowed oral intake. They identified that a participant had referred to a swallowing notice being changed behind the person's bed when a person's SLP recommendations was updated.

Members acknowledged that the assessment and management of dysphagia was tailored to the individual but highlighted what they perceived to be a lack of standardisation. For example, SVR members felt communication about the risks of developing pneumonia may have been lacking when one participant stated, *"there must have been something wrong that they not found out and how I found out I don't know … at that point pneumonia is a word I've heard" (P38)*. The SVR panel identified how the patient could not recall how he knew about the risk of pneumonia or if he had been told or read about it. This variance was perceived to extend to recommendations for alternative nutrition and the process of moving from an NGT to a PEG, and nutritional advice. Members felt patients and their informal caregivers were left "looking for answers".

SVR members felt it was also a lack of communication about how stroke can impact on a person's exercise tolerance, which accounted for why one caregiver complained that; *"I don't think she had enough physiotherapy" (P89)*. Members felt that the caregiver and the patient either did not recall or had not been informed about the fatigue effects of stroke.

4.4.3.6 Procedural Issues

This theme refers to procedural issues such as screening patients for dysphagia on admission in accordance with the national guidelines, and staff awareness of these procedures. There was an example where the procedures were not followed and one participant was offered food and drink before having their swallow screened despite their stroke being confirmed

and the informal caregiver referring to signs of swallowing difficulties. Members identified that the person was not initially nursed in a stroke bed, which may have been a reason for staff lacking awareness. This was perceived as lack of awareness of the stroke guidelines and “fractured care” between hospitals. Members identified how it was important for all staff, including non-qualified staff, to be dysphagia aware and to know how to thicken fluids to the recommended consistency. This extended to the importance of attention to detail and for staff to be aware of subtle changes in stroke patients, and how patients should be treated on a stroke ward with staff experienced in stroke.

4.4.3.7 The Unsaid

This section refers to questions which participants either did not respond to, or aspects of care, which were not raised that the SVR Panel identified as important and relevant to their own experience. For example, when asked about if they required assistance with cleaning their teeth, none of the participants raised this as a concern. For one panel member, lack of oral care had been a significant issue for his relative and was surprised that participants did not respond to this question. An alternative interpretation of this lack of response might be participants did not recall some events or it reflected their strength of feeling about oral care compared to other aspects of care during the acute phase. Another member identified that none of the participants raised the matter of taking their medication.

One panel member was surprised by the “lack of angriness” by participants. He perceived the participants’ gratitude to the care they received as “all-encompassing” and that participants may have been masking how they felt or were not being entirely congruent. In contrast, another member felt there were examples of “genuine gratitude” to the National Health Service and the care they had received

4.4.4 Discussion

This study provides a unique perspective of stroke patients' experiences of having their swallow screened and assessed during the first 72 h of post-stroke and subsequent days following. Six themes were identified. These included how past-future experiences may influence a person's emotional response to events; understanding what is happening and adjustment; the impact of dysphagia; attitudes to care; communication to patients and procedural issues. The findings highlight the importance of public health messages such as the FAST (Face, Arms, Speech, Time) (NHS, 2019) to help people detect and improve responsiveness to the needs of people having a stroke. It highlights how, despite these public health messages, people experience difficulty understanding what is happening at the onset of their symptoms and that there can be feelings of denial, which can lead to a delay in people's responsiveness to calling the emergency services. At an individual level, it also highlighted that some participants did not follow the public health message to telephone the emergency services, and instead went directly to the wrong hospital resulting in delayed admission to a stroke bed and receiving a specialist swallow assessment.

The inclusion of informal caregivers in the interviews provided a measure of validation to participants' responses and a caregiver perspective of events. Their participation not only highlighted the contribution informal caregivers make in supporting stroke patients in hospital, but also to patient safety by alerting staff to potential concerns (Merner et al., 2019), such as potential signs of aspiration. There were psychological consequences of their contribution characterised by feeling guilty after an adverse event and feeling cruel for implementing the SLP swallowing recommendations. Beyond the hospital environment, informal caregivers participated in dysphagia treatment by preparing foods to the recommended consistency and assisting with PEG feeding. The impact of living with a PEG had consequences for independence and social participation for the caregiver and the stroke survivor. The CONOCES study (Oliva-Moreno et al., 2018) highlighted the hidden cost of informal care and identified five indicators that predict the

heavy burden borne by caregivers of stroke survivors and the likelihood of risk of burn out. These indicators were the number of caregiving hours; the patient's health-related quality of life; the severity of stroke measured at discharge; the patient having atrial fibrillation; and the degree of dependence.

In addition to the impact of living with a PEG, participants reacted strongly to being prescribed thickened fluids and recommended modified diets. Bolus modification is often associated with worse quality of life (Swan et al., 2015). This study highlighted the potential nutritional and hydration impact of patients avoiding meals or drinks due to their dislike of the options offered and perceived lack of understanding regarding the importance of maintaining sufficient nutritional status as part of their stroke recovery. Participants who had an NGT communicated the pain and discomfort this caused. One informal caregiver felt that the dislodgment of the NGT and subsequent confirmation of its position by chest X-ray led to the prolonged time the NGT was needed. Throughout the time the NGT was disconnected, the patient would not have been receiving the nutrition they needed.

Effective patient communication in a format that is accessible is critical in healthcare. This is even more crucial for people affected by stroke who may experience aphasia as a consequence of stroke (Herbert et al., 2019). During the first 72 h post-stroke, patients have a multitude of tests and scans and are assessed by a range of professionals. Participants were aware of having these tests but struggled to recall what they were and when they were told about the risks associated with dysphagia and developing stroke-associated pneumonia. Poor communication can lead to compromises in patient safety and dissatisfaction in patients and caregivers (Vermeir et al., 2015). This was validated by the 'Stroke Voices in Research' panel. Other potential consequences of poor communication in this population is the risk of dehydration and malnutrition due to patients not understanding what foods and drink are suitable according to their dysphagia recommendations. The study also highlighted how a person's past experiences have the potential to impact on their emotional response and understanding of their condition and

treatment options. Time spent by clinicians finding out a person's case history can help inform and guide shared decision-making.

Patient and public involvement in health research is a well-established principle, meaning research is carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them (Hayes et al., 2012). Compared to advising on research questions and research design, the analysis and interpretation of research data is one of the less well-explored aspects of service user involvement in research (Locock et al., 2019). The SVR Panel helped enrich the themes identified by the researcher, checked the validity of the conclusions from a stroke survivors perspective and identified findings that were relevant to people affected by stroke, which the academic research team may have missed. The SVR identified the frequency of feeling words used by the participants to describe their emotional reactions to the stroke event and how they felt about the medical interventions and care processes. Panel members particularly empathised with the lack of communication to patients about the importance of maintaining adequate nutrition and hydration in accordance with the SLP recommendations, and they perceived a lack of standardisation in procedural issues and communication of the risk of pneumonia and the transition from short term to long term nutrition.

The National Standards for Public Involvement (NIHR, 2018) provide a framework for reflecting on and improving the purpose, quality and consistency of public involvement in research. These standards were used to reflect on what went well and how involving service users in data analysis could be improved for the future. Standard 1: inclusive opportunities, means offering public involvement opportunities that are accessible so that research is informed by a diversity of public experience so that it leads to treatment and services that reflect the needs of the service users. Examples of what went well included working closely with the SVR Panel Coordinator and sending information about the involvement opportunity to interested and relevant members of the SVR database, with a short description of what members could expect as part of the information they received. We identified and addressed barriers to members taking part. For example, members had

the option to request ‘book ahead’ transport so they did not bear any upfront costs and we made information available in different formats (Standard 4: Communications) so that it was accessible for needs of different people. We recognised that reading the transcripts might trigger feelings or emotions of the members about their own stroke experiences and offered emotional support (Standard 3: Support and Learning). For example, members were asked to be mindful about what they chose to share and knew that they could take a break from the focus group discussion and were shown a relaxation and rest room nearby where they could go if they wanted to spend some time alone or needed some one-to-one time with a member of the research team.

Involving service users in the analysis and interpretation of the data could have been further improved. Sometimes members brought up things from their own experiences, which had not always been raised by the interview participants. As part of the development of the group’s research skills, we used the group exercise to look for example quotes within the interview transcripts and explained how we had to be careful as researchers not to impose our experiences on what the participants had said and this was part of being a reflexive researcher. A learning outcome for the future would be to include more time for building research skills and discussion. This could be achieved by building on what we have learnt from this experience and actively learning from others who have involved members of the public in this stage of the research process, discuss support and training needs with new public contributors and involving public members in designing and delivering support and learning activities.

The authors acknowledge the potential limitations of the study. Firstly, the sample size is limited and reflects the opinions of a small group of stroke survivors and their informal caregivers. Secondly, the interviews took place in different settings and at different times during the stroke survivors’ pathway, which may have influenced their perspective of events in the first few days post-stroke. Thirdly, the primary author is a SLP, which may have blurred the insider-outsider boundaries of being a clinician and a researcher (Serrant-

Green, 2002). The main author had originally perceived that participants may struggle to recall events in the first 72 h post-stroke. This was the case with two participants. However, their informal caregivers validated what information they did provide or provided new information. There were occasions when the participant disclosed something that the researcher felt was their professional responsibility to pursue for reasons of patient safety or the interviewee sought the researcher's professional SLP opinion. When the latter occurred, the researcher maintained boundaries and requested the participant defer their question to their own SLP. Service user involvement in the analysis and interpretation of research data also helped to check the validity of the conclusions from a public perspective.

4.4.5 Conclusions

This interview study has explored patient and informal caregiver experiences of patients having their swallow assessed post-acute stroke as part of a mixed-methods design study. The research has identified six themes related to this topic, including how an individual's past-future experiences may influence their emotional response to the stroke; difficulty understanding what is happening at stroke onset and adjustment; the impact of dysphagia; attitudes to care; good and poor communication to patients; and procedural issues around screening for dysphagia. People affected by stroke were involved in analysing data and identifying themes, which were perceived as being relevant and most important to patients and their informal caregivers. The findings highlight the importance of effective public health messages to improve people's responsiveness to the signs of stroke, standardisation of assessment and management procedures, clear and effective communication to patients about the consequences of dysphagia, and the impact of dysphagia beyond the hospital environment.

The supplementary material is available in the Appendix D – Supplementary Material for the two interview studies (Page 299).

Chapter 5 Survey Design Methodology

Introduction

This chapter provides detail on the approach taken towards the integration and interpretation of the quantitative and qualitative data from the mixed methods study and the formulation of the survey questions. It includes the rationale for the quantitative study and the implementation of social exchange theory. It details what steps were taken to minimise potential sources of error, the process of building the survey on the online survey platform Qualtrics (Qualtrics, Provo, UT), and the testing of the survey. The chapter concludes by considering the ramifications of the COVID-19 pandemic.

5.1 Integration and interpretation of the quantitative and qualitative data from the mixed methods study

5.1.1 Integration of the results from the quantitative and qualitative data sets

The integration of the results from the different data sets of the mixed methods study (Chapter 4) involved a 3-stage process: Creating a joint display (Stage 1); identifying areas of convergence and divergence (Stage 2) and merging the data sets (Stage 3).

5.1.1.1 Stage 1 Creating a joint display

Stage 1 involved creating a side-by-side comparison of the quantitative and qualitative results in a table as detailed in Table 5.1. This was the beginning of

the inference process in the context of the study's purpose which was to inform the development of the topics and question objectives for a national survey.

As part of this process the results from the different data sets were framed within the findings of the systematic reviews, the relevant RCP Clinical Guidelines for Stroke (ISWP, 2016b) and the SSNAP performance indicators for dysphagia screening and specialist swallowing assessment. These theoretical pillars maintained the focus on the purpose of the survey which was to answer the research question and deciding what to include within the content of the survey design. An outcome of this process was the decision to focus the survey on four topics: (1) dysphagia screening, (2) dysphagia assessment and management, and two clinical care processes (3) nasogastric tube feeding; and (4) oral care.

Table 5.1 Side-by-side comparison of the quantitative and qualitative results from the case note review and interview studies framed within the SSNAP Key Performance Indicators and RCP Clinical Guideline for Stroke.

Topic	**SSNAP Key Performance Indicators**	**RCP 2016 Guideline**	**Systematic Review 1**	**Systematic Review 2**	**Case Note Review**	**Staff Interviews**	**Patient Interviews**
Dysphagia screening	Key Indicator 4.5 Percentage of applicable patients who were given a swallow screen within 4h of clock start.	Page 48. Paragraph 3.10 Acute Stroke Care - *There is good evidence that a multi-item dysphagia screening protocol that includes at least a water intake test of 10 teaspoons and a lingual motor test was more accurate than screening protocols with only a single item (Martino et al, 2014).* Page 86. Paragraph 4.16.1 Recommendation A *People with acute stroke should have their swallowing screened, using a validated screening tool, by a trained healthcare professional within*	SR1 - Variation in type and components of dysphagia screen, increasing body of evidence that EDS has potential to reduce risk of SAP.	-	Poor performance versus SSNAP key performance indicators, lack of staff trained in A&E and impact of patients who self-present vs. blue lighted to [name], DSP not consistently followed i.e. adhering to DSP protocol/paperwork, and risk/ consequences to patients of not being screened, staff roles who undertake the screen/first assess the patient.	Delays in dysphagia screening included patient factors:(a) patients who were not sufficiently alert, (b) patients who were medically unwell, (c) patients with subtle swallowing difficulties that were not initially identified and (d) stroke patients who had been misdiagnosed, staff factors: (a) lack of trained staff to screen patients in the ED, (b) time management, (c) lack of awareness	Procedural issues - Not following guidelines to keep patients NBM until screened by a trained professional, lack of staff awareness of RCP guidelines, future knowledge causing informal caregiver to reflect what should have happened. Attitudes about care - lack of recall about what, where, when the swallow test was.

Topic	SSNAP Key Performance Indicators	RCP 2016 Guideline	Systematic Review 1	Systematic Review 2	Case Note Review	Staff Interviews	Patient Interviews
		four hours of arrival at hospital and before being given any oral food, fluid or medication.				of the national guidelines, (d) pressure on the admitting stroke nurse to carry out the screen and (e) multiple admissions at the same time where the screen may be deprioritized if another patient required medical intervention (f) lack of ownership and monitoring screens had been done and service factors: (a) admission route (b) patient pathways (c) manner of referral (d) hierarchy of tests. Lack of standardisation in DSP used.	

Topic	SSNAP Key Performance Indicators	RCP 2016 Guideline	Systematic Review 1	Systematic Review 2	Case Note Review	Staff Interviews	Patient Interviews
Specialist Swallow Assessment	Key Indicator 4.6 Percentage of applicable patients who were given a formal swallow assessment within 72h of clock start	Page 48. Paragraph 3.10 Acute Stroke Care - *There is good evidence from a systematic review (Kertscher et al, 2014) that the investigation of dysphagia with instrumental assessments providing direct imaging for evaluation of swallowing physiology help to predict outcomes and improve treatment planning.* Page 86. Paragraph 4.16 *In patients with dysphagia on initial screening, a specialist swallowing assessment is indicated that includes consideration of function and*	SR1 - Lack of information about components of SLT assessment, no standardised assessment used such as MASA, evidence early SLP assessment may reduce risk of SAP (Bray et al. 2017), no evidence to justify routine use of VFS to screen for aspiration in acute stroke (Smithard et al., 1996), no study reported use of FEES. Lack of information about SLT management strategies.	SR2 - Instrumental assessment (as part of MDT approach to swallowing) may reduce SAP. Emerging evidence for screening for stroke immunosuppression and considering instrumental assessment in patients with low mHLA-DR expressions who have been identified with dysphagia.	DTP specialist assessment not being routinely included as specialist swallow assessment.	Delays in SLT assessment included patient factors: (a) patients who were not sufficiently alert, (b) patients who were medically unwell, (c) patients with subtle swallowing difficulties that were not initially identified and (d) stroke patients who had been misdiagnosed, staff factors: (a) lack of 7 day working by SLTs, (b) insufficient resource during periods of annual leave, (c) receiving late referrals in the working day, (d) documentation	Strong dislike of modified fluids/diet and impact on nutrition, perceived lack of communication about suitable foods for a modified diet, stroke survivors awareness of their swallowing abilities and what they can and cannot eat, perceived casualness of thickening drinks, informal caregiver implementation of SLT recommendations, informal caregivers lack of understanding of components of SLT

Topic	SSNAP Key Performance Indicators	RCP 2016 Guideline	Systematic Review 1	Systematic Review 2	Case Note Review	Staff Interviews	Patient Interviews
		cognition and a broader range of food and fluids of varying texture.				and (e) delays in onward referral following completion of the dysphagia screen, and service factors: (a) admission route (b) patient pathways (c) manner of referral (d) hierarchy of tests. Lack of standardisation - no SLT used a standardised assessment, consistency in components of SLT assessment but SLT's applied combination of clinical experience, knowledge and observation in how they approached each assessment.	assessment and rationale for recommendations. Staff undertaking SLT assessment - PPI member said in local hospital SLT assessment not always undertaken by SLT - shortage of SLTs. Good communication about rationale for dysphagia therapy.

Topic	SSNAP Key Performance Indicators	RCP 2016 Guideline	Systematic Review 1	Systematic Review 2	Case Note Review	Staff Interviews	Patient Interviews
						Variation in the consistency of fluids/diet that SLT might use to assess. Variability in resource - Accessibility and waiting times for VFSS/FEES. VFSS was more widely available than FEES but was not undertaken within the first 72 hours of admission. Difficulty accessing FEES were: (a) availability of staff competent to use the equipment, (b) problems with the equipment or (c) no equipment. Staff attitudes were identified as a barrier to FEES utilisation. 7 day	

Topic	SSNAP Key Performance Indicators	RCP 2016 Guideline	Systematic Review 1	Systematic Review 2	Case Note Review	Staff Interviews	Patient Interviews
						SLT service. Staff competencies.	
Nutritional Management	N/A	Page 71 Hydration and nutrition. Paragraph 4.7.1 Recommendation F. *Patients with stroke who are unable to maintain adequate nutrition and fluids orally should be: referred to a dietician for specialist nutritional assessment, advice and monitoring; be considered for nasogastric tube feeding within 24 hours of admission; assessed for nasal bridle if the nasogastric tube needs frequent replacement using locally agreed protocols; assessed for gastrostomy if they are unable to*	-	SR 2 - Equivocal evidence that NGT use increases SAP	Case Note Review - Examples of patient having repeated Chest Xray to check positioning of NGT, impact on patient's receiving nutrition.	Staff interviews – General consensus that number of times NGT could be inserted was 3 vs. holistic approach. Formal NGT protocol not standard. Reduced staff to check positioning of NGT> delays in feeding. Not all hospitals using bridle NGT.	Patient interviews - Pain on NGT insertion/ reinsertion, perceived poor communication to patients about rationale for PEG. Impact of PEG on social participation. Social participation of dining with others. Carer burden of PEG

Topic	SSNAP Key Performance Indicators	RCP 2016 Guideline	Systematic Review 1	Systematic Review 2	Case Note Review	Staff Interviews	Patient Interviews
		tolerate the nasogastric tube with nasal bridle. Recommendation H. *People with stroke should be considered for gastronomy feeding if they: need but are unable to tolerate nasogastric tube feeding; are unable to swallow adequate food or fluids orally by four weeks from the onset of stroke; are at high long-term risk of malnutrition.* Page 71 4.7 Hydration and nutrition - *In people requiring nasogastric tube feeding, delays in initiating feeding and frequent dislodgement can further affect nutritional status, although the use of nasal bridles may be*					

Topic	SSNAP Key Performance Indicators	RCP 2016 Guideline	Systematic Review 1	Systematic Review 2	Case Note Review	Staff Interviews	Patient Interviews
		helpful (Beavan et al, 2010). There is insufficient evidence to determine whether hand mittens prevent nasogastric tube dislodgement.					
Oral Care	N/A	Page 79. Paragraph 4.11 Recommendation A. *People with stroke, especially those who have difficulty swallowing or are tube fed, should have mouth care at least 3 times a day including: – brushing of teeth and cleaning of gums with a suitable cleaning agent (toothpaste and/or chlorhexidine dental gel), for which an electric toothbrush should be considered; – removal of excess secretions; –*	-	SR2 - Insufficient evidence for screening of aerobic Gram negative bacteria. MDT approach including specialist oral care and instrumental swallow assessment associated with reduced occurrence of pneumonia (Aoki et al., 2016)	Case Note Review - Current method (pink sheets) for recommending prescription of mouth care for NBM not being used (however a lot of the other boxes on pink sheets proforma were also not filled in)	Staff interviews - Hospital 4 had a formal oral care protocol. Subjectively felt to reduce number of datex relating to oral care. Hospital 5 Lack of uniformity in approach to oral care. Steps being taken to try and standardise the process. Adhoc use of specialist products. Hospital 2 Limited/no access to professional oral care. No prophylactic use	Patient Interviews - Lack of response to questions around mouth care. PCPI poor experience of oral hygiene

Topic	SSNAP Key Performance Indicators	RCP 2016 Guideline	Systematic Review 1	Systematic Review 2	Case Note Review	Staff Interviews	Patient Interviews
		application of lip balm. Recommendation B. *People with stroke who have dentures should have their dentures: – put in during the day; – cleaned regularly using a toothbrush, toothpaste and/or chlorhexidine dental gel; – checked and replaced if ill-fitting, damaged or lost.* Recommendation C *People in hospital or living in a care home after stroke should receive mouth care from staff who have been trained in: – assessment of oral hygiene; – assessment of oral hygiene; – selection and use of appropriate oral hygiene equipment*				of decontaminisation of the oral tract in any hospital.	

Topic	SSNAP Key Performance Indicators	RCP 2016 Guideline	Systematic Review 1	Systematic Review 2	Case Note Review	Staff Interviews	Patient Interviews
		and cleaning agents; – provision of oral care routines; – awareness and recognition of swallowing difficulties. Recommendation D *People with stroke and their family/carers should receive information and training in mouth care and maintaining good oral hygiene before transfer of their care from hospital.*					

A&E = Accident and Emergency, DSP = Dysphagia Screening Protocol, DTP = Dysphagia Trained Practitioner, ED = Emergency Department, EDS = Early Dysphagia Screening, FEES = Fibreoptic Endoscopic Evaluation of Swallowing, MASA = Mann Assessment of Swallowing Ability, MDT = Multidisciplinary Team, mHLA-DR = monocytic Human Leukocyte Antigen-DR, N/A = Not applicable, NBM = Nil by Mouth, NGT = Nasogastric Tube, PEG = Percutaneous endoscopic gastrostomy, PPI = Patient and Public Involvement, RCP = Royal College of Physicians, RHH = Royal Hallamshire Hospital, SAP = Stroke associated pneumonia, SSNAP = Sentinel Stroke National Audit Programme, SR = Systematic Review, SLT = Speech and Language Therapy, VFSS = Videofluoroscopic Swallowing Study.

5.1.1.2 Stage 2 Identifying convergence and divergence

Stage 2 of the integration process involved identifying areas of convergence and divergence from the different quantitative (QUAN) and qualitative (QUAL) data sets for each topic and creating a narrative description.

5.1.1.3 Stage 3 Merging the data sets

The final stage of the process was merging the two data sets, identifying points of agreement and difference, and linking these with examples from the data i.e. descriptive statistics from the case note review and quotations from the participant interviews and writing a comparative discussion (Stage 3). Table 5.2 illustrates the process of merging the data sets for each of the four topics of the survey.

Table 5.2 Merging the quantitative and qualitative data sets, identifying points of agreement and difference, and linking these with examples from the data and writing a comparative discussion for each topic of the survey

1 Dysphagia Screening	**Comparative discussion**	**QUAN DATA examples**	**QUAL DATA examples**
Points of agreement in comparing the QUAN and QUAL results	Convergent data revealed patients did not receive a dysphagia screen according to the specified criteria and there were risks associated with lack of awareness of the RCP Clinical Guideline for Stroke, and when guidelines were not followed (QUAN[1] + QUAL 2[1]). Potential reasons for patients not receiving a dysphagia screen within the recommended timeframe included patient (QUAN[2] + QUAL 1[2]+2[3]), staff (QUAN[3] + QUAL 1[4]+2[5]) and service factors (QUAN[4] + QUAL 1[6]+2[7]). Locally developed dysphagia screening protocols were used rather than published screens and there were variations in the components of the screen and models of screening (QUAN[5] + QUAL 1[8]).	47% (14/30) of patients screened within 4 hours[1] 17% (5/30) of patients too unwell/not alert for screen[2] 43% (13/30) of patients admitted on the weekend[3] 20% (6/30) of patients not directly admitted to a stroke bed[4] 56% (15/27) of screens completed by RN compared to 44% (12/27) by a DTP SN[5]	"Luckily he survived but if that domestic hadn't been there, who knows" (P35)[1] "Number 1 the reason I can see for delays is the patient's inappropriateness to complete the screen…they're not alert enough or not awake enough or medically not able to have it" (H4P1)[2] + "I didn't know anything really for two days. I was out of it you know with stroke. I just slept and slept." (P133)[3] "They don't have any trained nurses down there [ED] it's normally the [stroke nurse] that does it so only one person". (H5P4)[4] + "When nurses who should've known better than to give patients food and drink when they were admitted with a stroke did so" (SVR)[5] "Because it's so busy sometimes they don't get seen by a doctor for 4,5,6 hours so that has an impact on getting the screen quickly" (H3P4)[6] + "Nursing care is so fractured" (SVR)[7] "I can't understand why we've got so many different screens so much variance around the country" (H4P4)[8]
Points of difference in comparing QUAN and QUAL results	Patient interviews (QUAN 2) elicited more spontaneous descriptions of patients' experiences about having their swallow screened. There was variation in how much patients recalled about having the		"Tell you the truth I can't remember a great deal about it." (P89) "He did his swallow test with a little spoon… he tried to give me bit of water he got a banana, and he got some other bits… I'd get it in my

1 Dysphagia Screening	Comparative discussion	QUAN DATA examples	QUAL DATA examples
	screen, and the role of the professional carrying out the test.		mouth and then I'd have to get shut of it." (P151) "People been here all time I can't remember exactly who they are." (P151) "Well somebody did. I can't remember who it was." (P155)

2 Specialist Swallowing Assessment	Comparative discussion	QUAN DATA examples	QUAL DATA examples
Points of agreement in comparing the QUAN and QUAL results	Convergent data revealed not all patients received a specialist swallowing assessment within 72 hours of admission to hospital (QUAN[1] + SSNAP). Potential reasons for not receiving a swallowing assessment within the recommended timeframe included patient (QUAN[2] + QUAL 1[1] +QUAL 2[2]), staff (QUAN[3] + QUAL 1[3]) and service factors (QUAN[4] + QUAL 1[4]). Standardised swallowing assessments were not used (QUAL 2[5]). Instrumental swallowing investigations were not performed during the first 72 hours of admission (QUAN[5]+ QUAL 1[6]) Management included swallowing strategies and rehabilitation (QUAN[6]). Generally swallowing manoeuvres were not trialled during the first 72 hours	13% (4/30) of patients identified as at risk of dysphagia from the screen did not have a formal swallowing assessment < 72 hours of admission.[1] Reasons included patients attending emergency investigations and initially passing the dysphagia screen and being referred 72 hours post admission.[2] 43% (13/30) of patients admitted at the weekend.[3] 20% (6/30) of patients not directly admitted to a stroke bed[4] No patients received an instrumental swallowing	"If it's a stroke but atypical presentation… patient can go somewhere else…the patient might be fed…then realised patient is coughing or having difficulty…24-48 hour CT is done then realising there is a stroke" (H2P2)[1] "I can understand why sometimes these things get delayed and then they get forgotten - they might have been quite seriously ill to start with." (SVR)[2] "7 day working…so there's always going to be a day where's…no assessments to take place" (H2P3) "Sometimes they forget to follow the correct admin procedures" (H2P1)[3] "If they were in another hospital, it would be reliant on whoever they've got to screen or assess" (H1P1)[4] Perceived lack of standardisation about dysphagia assessment and management vs. tailoring to the individual (SVR)[5]

2 Specialist Swallowing Assessment	Comparative discussion	QUAN DATA examples	QUAL DATA examples
	(QUAN 1[7]) and in some cases not before assessing with instrumental assessment (QUAN 1[8])	investigation during the first 72 hours of admission. 1 patient was recommended FEES on Day 4 but it did not happen until 9 days later.[5] 7% (2/30) of patients were recommended oral trials[6]	"Possibly within the first week towards the end of the week but not within the first 7 days" (H3P1)[6] "I think giving them extra things to do and remember…is quite difficult…but I have tried chin tucks on the odd occasion when someone is quite alert" (H5P4)[7] "Generally I'm wary about advising people to do those things without them having an instrumental assessment" (H2P2)[8]
Points of difference in comparing QUAN and QUAL results	Data from QUAN and QUAL studies identified potential differences in professional groups trained to Specialist Level on the Inter Professional Dysphagia Framework to carry out Specialist Swallowing Assessments.	57% (17/30) of the specialist swallowing assessments were undertaken by a professional trained to Specialist Level on the Inter Professional Dysphagia Framework who was not a SLT.	Specialist swallowing assessments were carried out by SLT with exception of 1 hospital site which was the same site for the QUAN data (QUAN 1)

3 Nutritional management	Comparative discussion	QUAN DATA examples	QUAL DATA examples
Points of agreement in comparing the QUAN and QUAL results	Convergent data revealed there were instances of frequent NGT replacement and confirmation of placement by CXR (QUAN + QUAL 2[1]), perceived consequences (QUAN 1[2] + QUAN 2[1,3]) and variation in the number of times an NGT would be resited (QUAN + QUAL 1[4]).	1 patient attended CXR on 5 consecutive days to check placement and had also attended the same day for another reason.	"We had to have the tubes fitted several times because it dislodged…so then you have to go back down to X Ray to make sure it's in the right place…so that's probably lengthened the time that he would because of it" (P38)[1] "Going to different parts of the hospital where they pick up infection…and sometimes they miss out on a therapy session"(H3P1)[2]

3 Nutritional management	Comparative discussion	QUAN DATA examples	QUAL DATA examples
			Importance of sustaining adequate nutrition and hydration for avoidance of worsening stroke symptoms (SVR)[3] "So the policy is just been updated…to say maximum of 3 NG tubes within a 24 hour period" (H5P2), "There's no set number" (H3P1)[4]
Points of difference in comparing QUAN and QUAL results	There were no points of disagreement between the QUAN and QUAL data, but different points were highlighted from the patent-carer interviews, the staff interviews, and case note review. The case note review identified variation in the NGT feeding regime. The patient interviews (QUAN 2) elicited more spontaneous descriptions of patients' experiences of the discomfort of the NGT insertion[1], examples of perceived poor communication about the transition from NGT to PEG[2] and the impact of having a PEG beyond the hospital environment.[3] The staff interviews identified there was variance in the approach to re-siting NGTs, and strategies or interventions to prevent patients pulling out or dislodging NGTs.[4]	There was variation in the initial NGT feeding regime between; out of hours 20h continuous regime, dietician prescribed continuous feed and prescribed bolus feed. Time of NGT insertion was not consistently documented.	"Having it fitted was not very pleasant…having it there at times was quite painful because it would catch on different things (P38)[1] "And then they came a few days afterwards she said he'd have to have the PEG" (P35) ~ Perceived poor communication by the SVR group.[2] "I thought it cruel really… because he really loves his food and it's part of your social life" (P35)[3] "There is a place for a nasogastric tube bridle"(H3P1)[4]

4 Oral Care	Comparative discussion	QUAN DATA examples	QUAL DATA examples
Points of agreement in comparing the QUAN and QUAL results	Both data sets identified variation in approaches to oral care. The QUAN data identified the system in place for prescribing NBM patients oral care was not filled in and there was variation between hospitals that had an oral care policy and those that did not. Some hospitals had specific stroke care competencies and oral care was different for patients with dysphagia. There were differences in the frequency of oral care provided and the products used. One hospital had limited access to an oral care nurse. None of the hospitals used selective decontamination of the digestive tract.	0% (0/15) of NBM patients were prescribed mouth care on the SNS/HASU Nurse Assessment proforma.	"I don't think there's a formal policy there's no written policy" (H2P3) "The practice educator forum have asked for a…report to be submitted for each of the individual areas...because it seems like everyone is doing their own thing: (H5P2) "We wrote specific stroke mouthcare competencies" (H5P2) "Dysphagic patients would probably automatically be red on the oral care policy so they would have the Sage products" (H4P4) "Our aim is to offer it every couple of hours at least" (H1P2) Access to the oral care nurse "wasn't easy" (H2P3)
Points of difference in comparing QUAN and QUAL results	SVR group identified that patient and carers did not respond to questions about oral care although this was relevant to their own experiences.		"Took me back to my experience asked repeatedly" (SVR)

CT = Computer Tomography, CXR – Chest X-Ray, DTP SN = Dysphagia Trained Practitioner Stroke Nurse, ED = Emergency Department, HASU = Hyper Acute Stroke Unit, HP = Hospital Participant, NBM = Nil by Mouth, NGT = nasogastric Tube, P= Participant, PEG = Percutaneous Endoscopic Gastrostomy, RCP = Royal College of Physicians, RN = Registered Nurse, SLT = Speech and Language Therapy, SNS = Stroke Nurse Specialist, SSNAP = Sentinel Stroke National Audit Programme, SVR = Stroke Voices in Research, QUAL = Qualitative, QUAN =

5.1.2 Interpreting the merged data sets

The next stage of the implementation process was to interpret the merged findings of each topic to gain a more complete understanding of the data and to begin the process of identifying the question objectives for the survey to be able to formulate the questions to answer the question objectives.

5.1.2.1 Dysphagia Screening

The interpretation of the merged results found there was a lot of variation in dysphagia screening practice at multiple levels. There were different types of reasons and numerous reasons for delay in patients being screening on admission within the four-hour target.

The differences in dysphagia practice included: the model of dysphagia screening used (Swigert et al., 2007); the type of dysphagia screening protocols being used; the outcomes being measured; the methods of evaluation and the components of these protocols; different levels of screening within a hospital e.g. a basic versus advanced screen; staff trained to different competencies; and different professional groups involved. Types of reasons for delay included patient, staff and service factors. Table 5.3 illustrates the process of formulating the questions for the dysphagia screening topic.

Table 5.3 Question formulation for the topic Dysphagia Screening

Question Objectives	**Question formulation**
To find out what type of dysphagia screening protocols are being used and what is involved.	Does your stroke unit use a written dysphagia screening protocol? Is the dysphagia screen protocol a screen that was developed by your hospital, or a published dysphagia screen? Does the dysphagia screening protocol only use water (Level 0 Thin Fluids) i.e. 100% water? What is the maximum amount of water given? Which International Dysphagia Diet Standardisation Initiative (IDDSI) levels are included in the dysphagia screening protocol? Which IDDSI level consistency do you screen with first?
To find out which professional groups screen patients for dysphagia and are they trained to use the DSP.	Which healthcare professional typically carries out the dysphagia screen? Is it mandatory that the person carrying out the dysphagia screen has been trained to use the dysphagia screening protocol?
To find out about the onward referral process after the screen.	If the dysphagia screen identifies a dysphagia, is the patient referred for a clinical (bedside) swallowing assessment? If the patient is not referred for a specialist clinical (bedside) swallowing

Question Objectives	Question formulation
	assessment which health professional group continues to review the patient's swallowing problem after the dysphagia screen?
To identify the most frequent reasons for delays in patients being screened for dysphagia.	How applicable are each of these reasons for delays in stroke patients being screened for dysphagia in your stroke unit?
To find out about any other different variations in dysphagia screening practice.	Additional question at the end of the survey inviting participants to provide information about any other variations in dysphagia screening, assessment, and management during the first 7 days of a patient's admission to the stroke unit.

5.1.2.2 Specialist Swallowing Assessment and Management

There were both similar and different reasons for patients not being assessed by a specialist within the recommended time frame. In some instances, the delays in specialist assessment were the same patient and service factors as for the delays in screening. There were different staff factors identified as reasons for delay, including those related to resources such as lack of 7 day working of speech and language therapists (SLTs) and insufficient SLT staffing during periods of annual leave, and delays in onward referral following the screen.

There was variation in staff groups trained to carry out the initial specialist swallowing assessment, and standardised swallowing assessments, such as the Mann Assessment of Swallowing Ability (Mann, 2002), were not used. Instead, the professional carrying out the assessment tailored this to their own

knowledge, experience, and observation of the patient. Core components of the assessment included: a case history, checking the patient's baseline recommendation, liaising with nursing staff about suitability for assessment, cranial nerve examination and assessment with fluid and diet. There was variation in the consistency of diet and fluids that the professional would use to assess swallow safety. Instrumental assessments were not performed in the first 72hrs although there was potential for these to be carried out within the 7 days of admission. There was variation in the access to instrumental investigations and type used.

Management approaches included swallowing strategies and manoeuvres and rehabilitation of the swallow. Therapy including oral sensation therapy, therapeutic oral trials, swallowing exercises and hospital surface electromyographic (sEMG) biofeedback. Swallowing manoeuvres and sEMG were generally not trialled within the first 72 hours and, in some instances, only after they have been trialled in Videofluoroscopy clinic. Table 5.4 illustrates the process of formulating the questions for the dysphagia assessment topic.

Table 5.4 Question formulation for the topic Dysphagia Assessment

Question Objectives	**Question formulation**
To find out which professional groups carry out the clinical bedside swallowing assessment.	Which healthcare professional typically carries out the clinical bedside swallowing assessment?
To find out what assessments are being used for the clinical bedside swallowing assessment and what does it involve.	Does the stroke unit use a published dysphagia assessment for the clinical bedside swallowing assessment? What published assessment is used? If a published assessment is not used, are any other written guidelines used about what should be included in a clinical swallowing assessment? What does the first clinical bedside swallowing assessment typically involve? What International Dysphagia Diet Standardisation Initiative (IDDSI) levels are typically included in the first clinical (bedside) swallow assessment?
To find out what treatment options are typically recommended in the first 7 days of admission.	During the first 7 days of a stroke patient's admission, what treatment options are typically recommended on your Stroke Unit?
To find out about access to instrumental assessments and if they are routinely used if clinically indicated within the first 7 days of admission.	Does your stroke unit have access to Videofluoroscopy and/or Fibreoptic

Question Objectives	Question formulation
	Endoscopic Evaluation of Swallowing (FEES)? For those patients where it is clinically indicated, would your stroke unit routinely use these assessments within the first 7 days of a patient's admission?
To identify the most frequent reasons for delays in patients being assessed by a swallowing specialist.	How applicable are each of these reasons for delays in stroke patients receiving a clinical swallowing assessment in your stroke unit?

5.1.2.3 Nasogastric Tube (NGT) feeding

The length of time between when the decision was taken to non-orally feed and insertion of the NGT was unclear. There was variability in the approaches to NGT insertion and confirmation of placement. In the event of a patient dislodging their NGT, 3 times was generally the maximum number of times a replacement NGT would be passed, versus no set number and taking a more holistic approach. Service users highlighted the discomfort of NGT insertion, examples of poor communication about the transition from NGT to PEG and the impact of dysphagia and PEG beyond the hospital environment. Different strategies and interventions were used to prevent dislodgement. Delays associated with the commencement of NGT feeding was associated with confirmation of positioning. There were perceived consequences for not meeting planned nutritional intake and leaving the ward to attend X Ray to confirm placement. The initial NGT feeding regime varied between out of hours 20-hour continuous regime, dietician prescribed continuous feed and dietician prescribed bolus feed. Table 5.5 illustrates the process of formulating the questions for the NGT feeding topic.

Table 5.5 Question formulation for the topic NGT feeding

Question Objectives	**Question formulation**
To find out if hospital stroke units have a nasogastric tube feeding protocol and what does it include about placement and confirmation of positioning.	Does your stroke unit have a written nasogastric tube (NGT) feeding protocol? Are NGTs inserted overnight? How does your stroke unit check the position of the NGT before starting feeding? Does your stroke unit have a written protocol for the maximum number of times the NGT can be inserted? If yes, what is the maximum number of times reinsertion of the NGT is attempted in any patient?
To find out what is the duration from the decision to non-orally feed and the beginning of feeding by an NGT.	In patients who are unable to maintain adequate nutrition and fluids orally, typically what is the number of hours from when the decision is taken to non-orally feed and the beginning of feeding by an NGT?
To find out what is the standard position for NGT feeding.	What is the standard position in which the patient is positioned during NGT feeding?
To find out what management strategies are used to prevent inadvertent NGT removal.	In cases of inadvertent NGT removal, what management strategies does your stroke unit typically use?

5.1.2.4 Oral Care

There were differences in methods for identifying, prescribing and actioning oral care. Some hospitals had an oral care policy and specific stroke care protocols for patients with dysphagia. There were differences in the frequency of oral care provided and the products used and there was limited access to professional oral care. None of the hospitals used selective decontamination of the digestive tract prophylactically to minimise SAP. Table 5.6 illustrates the process of formulating the questions for the oral care topic.

Table 5.6 Question formulation for the topic Oral Care

Question Objectives	**Question formulation**
To find out if hospital stroke units have an oral care protocol and if this protocol is specific to stroke patients.	Does your stroke unit have a written oral care protocol? Is this protocol a hospital oral care protocol or a specific protocol written for the oral care of stroke patients?
To find out if there any differences in the provision of oral care for patients in hyper/ acute stroke compared to other parts of the stroke pathway and what are the differences.	Are there differences in oral care provision for patients in the hyper/acute stroke unit compared to those patients in other parts of the stroke pathway? How is oral care provision in the hyper/acute stroke unit different to that provided post-acute phase stroke?
To find out if there any differences in the provision of oral care for patients with dysphagia and what are the differences.	Are there differences in oral care provision for patients with dysphagia? What are the differences in oral care provision for people with dysphagia

Question Objectives	Question formulation
	compared to the provision for those people without dysphagia? How often each day is mouth care typically provided to people with dysphagia on the stroke unit?
To find out what staff groups provide oral care and are staff trained in oral care of stroke patients.	Which staff group typically provide oral care? Do staff receive training in oral care? Is the training staff receive specific to the oral care of stroke patients?
To find out what type of training in oral care do staff receive.	What type of training do staff receive? Is the training staff receive specific to the oral care of stroke patients?
To find out what does oral care involve.	What does oral care typically involve on the stroke unit?

5.2 Rationale for the Quantitative Study

The rationale for the quantitative study was to gather and measure structured data on the variables of interest, using a survey instrument. A survey was identified as the best method to explore variations in practice at a hospital level and establish cause and effect relations among the target variables. The sample frame for the national survey was Routinely Admitting and Non-Routinely Admitting Acute Stroke Hospital Teams in England and Wales registered on the SSNAP register. Non-routinely admitting acute teams are teams that do not generally admit stroke patients directly but continue to provide care in an acute setting when patients have been transferred from their place of initial treatment. Hospital teams were included if they were registered on the SSNAP register for October-December 2019 and had sufficient records/data to report, and were an active Hyper/Acute Stroke Unit. The SLT Clinical Acute Stroke Lead, was

identified as the professional best placed to capture data about dysphagia management and related clinical processes, at an organisation level, in each acute stroke unit. The survey responses from each hospital would be linked to hospital level data on the SSNAP register and statistically analysed for associations with incidence of SAP using regression analysis. Further detail about the statistical analysis is detailed in the Statistical Analysis Plan in Chapter 6.

5.3 Theoretical Approach

5.3.1 Tailored survey design

A tailored survey design approach was used (Dillman et al., 2014). Tailored survey design is a strategy that can be applied to all aspects of survey design to improve the quantity and quality of survey responses, and to reduce survey error specifically including: coverage error, sampling error, measurement error and non-response error. Tailored survey design evolved and replaced the total design method (Dillman, 2008), and encompasses postal, telephone and internet and mixed mode surveys.

Tailored survey design uses social exchange theory to identify ways to improve the quality and quantity of survey responses by organising the data collection process in a way that the respondent trusts that the benefits of responding will outweigh the costs. It also recognises that, to obtain survey responses, different survey procedures need to be used to obtain response from different populations, on different topics and in different survey situations.

A key premise of tailored survey design is that there are no single set of procedures that can be applied to every situation. Instead, a customised set of survey procedures are required based on the knowledge and sponsor of the survey, the types of people who will be asked to complete the survey, recruitment procedures, resources available and the time frame for reporting results. These processes need to interact and work together to build social exchange and encourage those surveyed to respond.

5.3.2 Social exchange

Social exchange as a theory for small group research was first suggested by the sociologist George Homans (Homans, 1958). Social exchange theory is a

conceptual way of understanding how people behave in their interactions with one another as they implement a cost versus benefit assessment to weigh up the values and costs of that relationship, and whether to choose to continue that relationship (Dillman et al., 2014). In relationships, parity is often based on partners seeking equilibrium where the ratio of reward is proportionate to the degree of cost for both partners. The interaction is disturbed if there is inequity in the relationship (Redmond, 2015). Social exchange provides a framework to explain how human beings want to find meaning through relationships with others and want to achieve self-interests from which they also draw satisfaction. Social exchange theory includes broader social realms that include how human interaction is influenced by culture, tradition, and social norms.

5.3.2.1 Social exchange and survey methodology

Social exchange theory is used by survey methodologists to understand the decisions people make about whether to respond to surveys (Lavrakas, 2008) and provides guidance for designing the data collection process (Dillman et al., 2014). It can also be useful in both explaining sample characteristics such as personal topic interest and attitudes towards survey research, and web design attributes, such as unconditional incentives and questionnaire length (Keusch, 2015).

The application of social exchange in survey design encourages the researcher to think about the multiple aspects of how a request from a stranger is viewed, and what features of that request, may influence whether a questionnaire is completed and returned. The decision to participate and continue to participate involves numerous considerations that consider perceived benefits, costs and trust.

Dillman et al. (2014) emphasise trust is the base upon which the decision to respond depends. Obtaining a response will be most likely if the respondent can

trust that the promised benefits will come to fruition and if the perceived costs have been minimised such that the benefits outweigh the costs. Social exchange provides a framework to think how multiple features of the survey such as: the legitimacy of the request, modes and timing of contacts, content of communications, questions asked, question order and presentation, connect together to improve response and quality of data.

5.3.2.2 Applying social exchange concepts in practice

The following evidence-based techniques were used as part of the total survey design to minimise nonresponse bias by motivating participants to go from invitation request to response.

5.3.2.2.1 Increasing the benefits

The benefits of responding to a survey are potentially limited. Responding is voluntary and can be easily disregarded. There are ways that a survey can be designed to increase the modest benefits that some people may feel when responding to survey requests (Dillman et al., 2014). Using benefits can also have an additive effect, such that using several of them have the potential to increase response rates over and above using only one, and certain features can act as a way for allowing other aspects to have a positive impact.

The potential respondents belonged to a group of stroke speech and language therapists (SLTs) who are responsible for the assessment and management of dysphagia of patients in the hyper acute phase of their stroke. Health and care professionals working in the clinical specialty of Stroke feel part of a community whose aim is to improve the health and wellbeing of people affected by stroke. The degree of societal cohesion is one of the societal-level factors identified by Groves et al. (1992) that influence participation in self-administered surveys. Many people feel a significant benefit from contributing to something that they

perceive will benefit others. The benefits of how the results will be useful were communicated to the respondents, to encourage them to respond.

Acute stroke SLTs have a specialist role and occupational skills in the assessment and management of stroke patients with dysphagia. The SLT Acute Stroke Clinical Lead was identified as the most knowledgeable person to provide information about organisational practice about the assessment and management of dysphagia in acute stroke patients. When people are asked for assistance that they can provide, it conveys the value of their contribution, and people take interest from being asked (Dillman et al., 2014). Communication with the participants stated that the SLT Acute Stroke Clinical Lead has been specifically selected for their specialist knowledge and that only the SLT Acute Stroke Clinical Lead is being surveyed in each hospital. Telling respondents that only a small number of people have the opportunity to respond can be perceived as doing something more valuable.

Asking topically relevant questions that may be of particular interest to respondents may be seen as a benefit to answering a survey, and strategically ordering questions so that those with broad appeal and interest appear earlier in the questionnaire, help to engage people early in the questionnaire. Questions were grouped by topic with questions about dysphagia screening and clinical bedside swallowing assessments being strategically placed at the beginning of the questionnaire with questions about multi-disciplinary swallowing management appearing later.

Providing a token incentive in advance can encourage compliance with a request to complete a survey by creating an expectation of reciprocity or sense of obligation. A pre-paid monetary or non-monetary incentive have been shown to be one of the important ways to provide benefits to complete surveys. This is because the recipient feels it appropriate to return the favour by completing the questionnaire even though it is not required or mandatory. For this survey a

non-cash incentive was employed. Participants were offered a postal copy of the survey and told that if requested, a stamped address envelope would be provided to return the completed questionnaire.

In addition to using these techniques, a mixed mode design was used which involved multiple contacts, different modes of communication and ways of responding. Mixed mode surveys have the potential to improve the effective application of social exchange theory in ways that will improve survey response and data quality. Mixing modes of data collection is also a way of trying to minimise sampling error by trying to take advantage of the strengths of certain modes to overcome the weakness of others. It can also be a way of reducing costs of the survey by collecting as many responses as possible in a more cost-efficient way (e.g. online) before switching to a more expensive mode (e.g. postal) to try and obtain additional responses. Using different modes can be a way to increase coverage or offering people an alternative mode may be particularly appealing if the respondent has a preferred method of response. Multiple types of contact in different modes that work together to produce a combined effect may convince respondents to respond.

For this study, the method of distribution involved multiple contacts and different response modes. This included offering a web mode survey first, and two email reminders, with the option of a postal survey being offered on the last contact. Offering simultaneous choice of response modes has been shown to lower response rates compared to offering the different modes sequentially (Millar and Dillman, 2011). This was adapted from the initial plan which was to use an email augmentation of a multiple postal contact strategy. This is when a primary postal contact is made and is incorporated with supportive emails which include an electronic link to the survey. The last contact was to be a postal reminder with paper questionnaire. Millar and Dillman (2011) believe sending a postal invitation to a survey is more desirable than sending an email invitation as official institution stationery can signal the importance and legitimacy of the

study. The original plan was changed to offering a web mode survey first with the option of a postal survey later in response to the Research Ethics Committee (REC) concerns not only about repeat contacts, but also in response to COVID-19. The impact of COVID-19 on the mode of communication and timing of contacts, and its potential effect on response behaviour response is discussed later in this chapter.

5.3.2.2.2 Decreasing the costs

The costs of responding to a survey can be substantial for respondents. The main cost is long and detailed surveys, with questions that the respondent does not understand, cannot answer, or considers inappropriate to provide. Other burdens include objections to the mode of the survey, frustration with how often the surveyor attempts to contact the respondent and the feeling of being inconsiderate of people's time (Dillman et al., 2014). There are ways to minimise non-response before it happens.

The recommended length of a questionnaire varies by mode and type of survey. Blair et al (2014) recommend that a web survey takes less than < 15 minutes. As part of the iterative process of writing the survey questions, the research team checked themselves from adding any questions that may have been driven by the research team's interests rather than what had been generated by the research data.

Asking detailed questions or requesting detailed responses which makes it difficult for the respondent to respond, increases the sense of burden. The researcher tried to reduce the level of burden by only collecting the level of detail needed. Questions were only asked that were necessary to do the analysis to answer the research question that motivated the survey in the first place.

Enhancing visibility and minimising respondent burden can decrease the costs of responding. Qualtrics (Qualtrics, Provo, UT), an electronic survey tool, was used to build the survey. The software offers suggestions of how to optimise efficiency and spaces the questions evenly. Other elements of visual design which were incorporated included grouping and organising the information on the screen, segmenting the topics, choosing an accessible font, inserting a hover button to provide a more detailed definition of a question to avoid a lengthy definition on the page.

Offering respondents a desired way of responding, or avoiding asking respondents to respond in a survey mode that is uncomfortable, can help decrease costs by making it easier to respond. Respondents were provided with a hyperlink that opened the browser to the survey when clicked. A postal copy of the survey with a stamped address return envelope was offered for respondents who may have preferred to respond by mail.

5.3.2.2.3 Building Trust

Trust is an increasing problem with internet surveys from unknown sources. The relationship between invitation sender and recipient, familiarity of sponsor, trust in the sponsor, reputation of sponsor and survey provider and the authority of the sender influence the participation decision (Keusch, 2015). The legitimacy and positive relationship that the Stroke Association has with this community of clinicians can produce a sense of reward and that responding can be seen as doing something helpful.

The researcher's relationship with the Stroke Association was utilised in the invitation letter and reminders. This was done by telling the respondents that the research was funded by the Stroke Association and branding the communication materials, the survey, and email subject line with the Stroke Association logo. The use of the academic institution letterhead provided

assurance of confidentiality and data protection and, by providing the contact name of the researcher, the Director of Studies and the name of the person to contact if they have any concerns about the study, would help to foster trust in the request.

Email recipients are more likely to open messages that come from individuals whose name they recognise (Tuten, 1997). Trust was built through the development of the contact list for the survey. The distribution list was created from the researcher and research team existing relationships, dissemination activities at conferences and online forums, and clinical academic networks. Building the distribution list for the survey is one of the ways that the survey used the concept of tailored survey design to reduce survey error, by customising the survey based on the researcher's knowledge of the topic, the funder, the type of people that are being asked to complete the survey, and the resources available.

5.4 Steps taken to minimise other sources of survey error

5.4.1 Coverage error

Coverage error refers to the property of the sampling frame. This is when the list from which the sample respondents is drawn does not accurately measure the population or the characteristic being measured. The population for this survey was SLT Acute Stroke Leads working in routinely and non-routinely admitting hospital stroke units in England and Wales that were registered on the SSNAP database. The SSNAP database includes 95% of all hospital teams in England, Wales and Northern Ireland and was the sampling frame from which the hospital stroke units were drawn as part of the process for identifying the SLT Acute Stroke Lead in the hospital stroke unit. Using the national stroke register ensured accuracy that the routinely and non-routinely admitting teams in England and Wales were included.

5.4.2 Sampling error

Sampling error is when the sample surveyed does not represent the population. Sampling error may have occurred if a sub set of the SLT Acute Stroke Leads from hospitals registered on SSNAP were surveyed. A decision was made to include all the hospital teams due to the relatively small number compared to a larger population type survey. If the decision had been to send out the survey to a sample of the routine and non-routinely teams, a power calculation would have been done.

5.4.3 Measurement error

Measurement Error is the difference between the estimate produced and the true value because respondents are unable or unwilling to provide accurate answers which can be due to poor question design, survey mode effects, interviewer and respondent behaviour, or data collection mistakes. Measurement error was minimised by adopting a tailored survey design approach. Further steps to minimise data collection mistakes involved piloting the survey, using the Qualtrics survey tool to automatically capture the data and exporting the data, directly to SPSS for Windows for analysis.

5.5 Using the Qualtrics Survey Tool

The Qualtrics online survey tool was used to build the survey and collect respondent data.

5.5.1 Setting up and organising the survey

Question blocks were used to organise the survey questions into distinct categories: information about the survey; the name of the hospital; and topics of the survey. Each block was labelled to make it easier to understand when the data were exported for analysis. Specialist computer support was used to write a Java Script to create a drop-down menu for participants to be able to select the name of their hospital from a drop-down menu of hospital teams registered on the SSNAP data base. There was an alternative facility that allowed the respondent to type in the name of their hospital in the box provided. This was in case the respondents used a different name to the label that was used by SSNAP (e.g. RVI instead of Royal Victoria Infirmary).

5.5.2 Creating questions and question types

For each survey question, different question answer formats were selected, for example, text entry, multiple choice, or matrix style questions depending on the question. Matrix questions were used for questions that used a Likert Scale that allowed respondents to rate the specific options provided. A forced validation response was chosen for each question, such that respondents were required to provide an answer before they could proceed to the next question. There was a back button which allowed participants to go back, review and change their responses.

Different types of survey logic: skip logic, display logic and branch logic were applied. Logic refers to how you want the survey to react based on what answer

the participant gives. Skip logic is when participants must respond in a particular way to be shown the next question. For example, if a respondent were to answer ‘no’ to the consent statement they would be skipped forward to the end of the survey. Display logic is when a question is displayed dependent on whether the participant meets a certain requirement. For example, dependent on whether a participant responded ‘yes’ or ‘no’ to a preceding question, the following question may or may not be displayed. Lastly, branch logic was used to divert the participant to a different block of questions depending on the condition set.

5.6 Survey distribution

An anonymous electronic link to the survey was created which was pasted into an email message and sent to each participant on the distribution list and completed survey response exported to SPSS for Windows (Version 26.0) predictive analytics software for analysis.

5.7 Piloting the Survey

A pilot was carried out to identify any questions or vocabulary that was ambiguous or difficult to understand and to make sure that the words in the questions conveyed consistent meaning so that respondents had a common understanding of the question they were being asked. Ambiguous questions might cause respondents to interpret the question differently and not provide an answer that meets the question objective. Secondly, the purpose of the pilot was to identify any complexities or difficulties answering the questions. Potential respondents may be discouraged to answer questions that they feel unwilling or unable to respond. The third reason was to identify any typographical errors or instructions that may be unclear. Further reasons for piloting the survey included finding out how respondents may approach or perform the task of answering the

question, finding out how long the survey took, and finally to identify any practical problems with the survey.

The pilot involved a four-stage developmental process: testing the usability and technical functionality of the electronic questionnaire (Stage1); pilot phase (Stage 2) where a sample of the target population and clinical researchers completed the survey and were asked to respond to six debriefing questions; final refinement based on the pilot feedback (Stage 3) before fielding the questionnaire to the target population (Stage 4). The distribution of the survey is reported in Chapter 6.

5.7.1 Stage 1 – Testing the useability and technical functionality

Members of the research team were sent a hyperlink to the e-survey and provided with an excel spreadsheet with separate worksheets that reflected different question routes dependent on the question choices selected. Each worksheet had written instructions indicating the question number and written question, the type of question (for example, a yes/no question, or single, multiple choice or text response), the target response and a comments box to enable question by question feedback. The survey topics were colour coded for visual accessibility.

Three members of the research team independently tested the different questions routes. Feedback from the question flow testing included: technical issues such as not being able to use the hover function over the information symbol when completing the survey on a mobile device; suggested changes to the wording of a question to make it more understandable; grammar and spelling errors; issues to do with the display of questions based on an earlier response given and questions which provided an ‘Other’ option.

One researcher identified questions that had an ‘Other’ option with a free text box, that respondents could tick ‘Other’ and proceed to the next question without providing a description. After this had been corrected another member identified that for matrix type questions which had a list of statements that included ‘Other’, that the respondent was forced to write something in the free text box in order to continue.

5.7.2 Stage 2 – Pilot Phase

A purposeful sample of 8 registered SLTs, and members of the Research Team who had not been involved in the question flow testing, was used for the pilot. Table 5.7 presents the characteristics of the pilot sample population. Registered SLTs included those who would be the target population for the survey and SLTs with clinical-academic backgrounds in post stroke dysphagia. The pilot phase ran between 12th June-5th August 2020.

Table 5.7 Characteristics of the pilot sample population

Participant	Clinical B/ground	Clinical-Academic B/ground	Region	Rationale for inclusion
P1	SLT Acute Stroke Lead	Clinical	London SCN	Target population for survey /Works in a Centralised Stroke Unit/ Consistent with strategy for identifying sites for staff interviews.

Participant	Clinical B/ground	Clinical-Academic B/ground	Region	Rationale for inclusion
P2	SLT Acute Stroke Lead	Clinical-academic (Post Graduate researcher)	East Midlands SCN/Trent Dysphagia CEN	Target population for survey
P3	SLT Acute Stroke Lead	Clinical-academic (PhD)	East Midlands SCN/Trent Dysphagia CEN	Target population for survey
P4	SLT Acute Stroke Lead	Clinical-academic (PhD)	Yorkshire and The Humber SCN	Target population for survey
P5	SLT Stroke Lead	Clinical-academic (PhD)	Yorkshire and The Humber SCN	Target population for survey (non-routinely admitting acute team)
P6	Registered SLT/Early Supported Discharge	Clinical-academic (PhD)	Thames Valley SCN	Able to provide a different hospital perspective. Experience of Acute Stroke.
P7	Registered SLT/Stroke Rehab	Clinical	Yorkshire and The Humber SCN	Accessibility of survey. Able to

Participant	Clinical B/ground	Clinical-Academic B/ground	Region	Rationale for inclusion
				provide a different hospital perspective.
P8	Registered SLT/Previous experience of Acute Stroke	Non-clinical (D4D)/MSc Clinical Research	Yorkshire and The Humber SCN	Accessibility of survey. PI in post stroke dysphagia research
P9	Supervisor	Stroke Physician/ Professor	Greater Manchester & Cheshire	Research team
P10	Supervisor	Former Research Lead for SSNAP/ Physician	Not applicable	Research team

SCN= Strategic Clinical Network, CEN = Clinical Excellence Network

Sample respondents were provided with a series of debriefing questions:

1. **Did you find any questions hard to read?** 'Hard to read' questions refer to the lexical difficulty of the question and wanting to make sure that the key terms/words used in the question are commonly used/easy words as opposed to rare/less frequently used words. It also refers to the structure and length of the question (i.e. syntactic difficulty) and avoiding the use of unnecessarily long and complicated sentences, where possible.
2. **Did you have problems understanding any of the questions?** This refers to the understanding of the meaning of the question and identifying any questions or terms that may be ambiguous or difficult to understand. The researcher wants the respondents understanding of the terms used to be the same as that intended, and to identify if there is a need for any definitions.
3. **Were there any questions that you had difficulty providing an answer for?** Barriers to knowing the answers may include not having the information to answer the question, having the information but being unable to remember the information accurately or in sufficient detail to answer the question or difficulty in accurately placing events in time.
4. **Were there any questions which made you uncertain about what the appropriate answer was?** The researcher wants to avoid the respondent feeling they have to give an inaccurate answer to a question because they were unsure about the appropriate answer.
5. **Did the question/question style provide you the opportunity to give the appropriate answer?** This refers to those questions which specify the form of the answer. It is about ensuring that the answer task allows the person responding to give the true answer to the question.
6. **Were there any other issues that posed problems?** This refers to any other problems or challenges that the respondent may identify which did not fall into the above categories.

The researcher acknowledges that sending out the electronic survey and asking respondents to replicate the survey by completing the survey and answering debriefing questions provides limited information about how respondents approach the question-and-answer process. This was mitigated by following up pilot respondents' comments by email to find out more about the question-and-answer process, for those questions that were not consistently and reliably understood.

5.7.3 Stage 3 – Refinement based on the pilot feedback

Seven out of the 10 of the potential sample respondents responded to the request to pilot the survey. Six respondents were registered SLTs, and one was a member of the research team. Not all respondents provided feedback to the questions or responded to each question separately. Some respondents grouped their feedback. Where this occurred, the researcher assigned their comments under the most appropriate question. In some instances, respondents' feedback about the same issue was answered under the heading of a different question. In these instances, the researcher reported the feedback under one debriefing question.

A summary of the respondent feedback and the refinement process and actions taken based on the respondent's feedback is detailed in Appendix E Summary of pilot survey respondent feedback. The final version of the survey (Appendix F Published electronic version of the survey) included 51 questions grouped by topic: dysphagia screening, specialist swallowing assessments and management, nasogastric tube feeding and oral care processes. Questions were hidden or revealed based on previously answered questions. Where there was the potential for primacy effects with visual delivery, this was overcome by avoiding certain question formats. Missing data were minimised by using a forced response option. The predicted duration of the survey was 15 minutes. The distribution of the survey is described in the next chapter.

5.8 Ramifications of COVID-19 on the survey design and potential response behaviour

After submitting an amendment to the Research Ethics Committee on 24th January 2020, the World Health Organisation (WHO) declared the outbreak of COVID-19 a 'Public Health Emergency' on 30th January and on 11th March, COVID-19 was characterised as a pandemic. Acknowledging the sub-committee's concerns about repeat contacts, tailored survey design theory and trying to balance this with the exceptional COVID-19 situation, the researcher felt that the REC suggestion of a maximum of two contacts was not sufficient. A counter proposal of three attempts to recruit on the web, the third being a delayed email reminder, if necessary, and with the offer of a sending a postal survey for those who may prefer to respond in that way was approved. The change in strategy from deploying a primary postal contact was that the SLT Acute Stroke Clinical Leads may be working remotely or be temporarily redeployed to other clinical settings.

One of the implications of the COVID-19 pandemic on research data collection was that face-to-face interviews were not allowed to take place, such that researchers wanting to collect data needed to find ways to work within the new situation. Many researchers looked to collect data remotely via online platforms and telephone. Although a web survey was always identified as the data collection method in the research protocol, the fact that more researchers were using this as a method of data collection meant that it was likely that survey respondents would receive more web survey invitations which might potentially lead to lower participation (Porter et al., 2004; Keusch, 2015). Homans (1958) social behavioural theory that the more a man gets the less valuable any further unit of that value is to him, and the less often he will emit behaviour reinforced by it, can be applied to over-surveying people. Although the face-to-face interview restriction was lifted before the main survey was distributed, there was the potential for those researchers who had changed their data collection

method to continue to use remote forms of data collection, and for respondents to feel satiated.

The pandemic had the potential to impact on respondent behaviour due to increased clinical pressures and online communications about COVID-19. As the participants for the survey are frontline clinical staff there was the potential for clinicians' capacity to participate in research activities to be reduced as they responded to the clinical demands of COVID-19. The researcher's personal experience included returning to clinical care and redeployment into areas of the speech and language therapy service where there was the greatest clinical need. The Stroke Association supported the NHS to respond to the pandemic by enabling clinical and academic health and care professionals to return to clinical care where requested to do so by their employing organisations. In addition to the clinical demands that COVID-19 placed on SLT Acute Stroke Clinical Leads, staff were receiving an increased volume of COVID-19 related emails which potentially reduced their capacity to respond to online web survey invitations. There were also reports of clinical frontline staff feeling demoralised and exhausted which has the potential to impact on response levels (RCSLT, 2020).

Chapter 6 Survey Results

Introduction

This chapter includes the statistical analysis plan and the published paper about the survey results (Eltringham et a., 2021). The statistical analysis plan is registered on the ClinicalTrials.gov website (Identifier: NCT04779710). The statistical analysis plan and the published paper are presented in their published versions.

6.1 Statistical Analysis Plan

6.1.1 Research background

Stroke-associated pneumonia (SAP) is a common post stroke infection affecting 14% of patients (Kishore et al., 2015) and is associated with an increased risk of hospital mortality (Westendorp et al., 2011) and prolonged hospital stay (Finlayson et al., 2011). The combination of stroke-induced immune-deficiency and aspiration of oropharyngeal secretions and gastric contents into the lungs secondary to impaired consciousness and dysphagia predisposes patients to SAP in the first few days post stroke (Hannawi et al., 2013). Patients with dysphagia with confirmed aspiration have an 11-fold increased risk to SAP (Martino et al., 2005). However, up to half of patients with SAP do not aspirate (Westendorp et al., 2011), which reflects SAP's multifactorial pathophysiology.

There is wide variation in the assessment and management of dysphagia in acute phase stroke and there is the potential for a range of medical interventions and clinical processes to be associated with risk of SAP (Eltringham et al., 2018; Eltringham et al., 2020). This research aimed to find out how methods of dysphagia assessment and clinical management during the first 72 hours of admission to hospital affect the risk of stroke patients developing

SAP and what care processes and interventions specific to patients with dysphagia affect the risk of stroke patients developing SAP during acute phase stroke.

6.1.2 Research question

How does variation in assessment and management of dysphagia in acute stroke affect development of stroke-associated pneumonia?

6.1.3 Hypotheses and rationale

6.1.3.1 Hypothesis 1 - *There is no difference in incidence of pneumonia using a dysphagia screening protocol that uses 100% water compared to a dysphagia screening protocol that uses water and other consistencies (Null hypothesis)*

There are a range of dysphagia screening tools used and different methods of evaluation (Eltringham et al., 2018). Some hospitals used standardised screens; others use local dysphagia screening protocols. Some dysphagia screens evaluate patient characteristics and do not involve screening the patient with any water or food, some screens involve water only and others screen with water and different fluid and or diet consistencies. UK Clinical Guidelines state there is good evidence that a multi-item dysphagia screening protocol that includes at least a water intake test of 10 teaspoons and a lingual motor test is more accurate than screening protocols with only a single item (ISWP, 2016b). No single tool has achieved consensus as a standard screen (Daniels et al., 2012).

6.1.3.2 Hypothesis 2 - *Using written guidelines for the first specialist clinical bedside swallow assessment will not be associated with incidence of pneumonia (Null hypothesis)*

Clinical bedside swallow assessments are undertaken by specialist trained healthcare professionals. A high degree of variability has been reported within the clinical bedside assessment process and in practice standardised assessments are less frequently used. Observation of practice has found that variability in reported practice is likely the result of a nuanced patient-centred assessment process characterised by iterative cycles of information gathering in order to generate and test clinical hypotheses and that there may be unintended negative consequences of solely relying on data generated from standardised assessment tools (McAllister et al., 2020).

6.1.3.3 Hypothesis 3 - *Hospital Teams that insert Nasogastric Tubes (NGTs) overnight have increased risk of SAP compared to Hospital Teams that do not insert NGTs overnight.*

Evidence that nasogastric tube (NGT) placement increases risk of SAP is equivocal (Eltringham et al., 2020). Placement of NGT 'out of hours' has been the subject of a national patient safety alert advice. Nasogastric tubes should only be placed when senior support for placement and placement confirmation is readily available. The rationale for this was the greater risk of error by junior and less experienced staff confirming NGT placement in evenings and at night (NHS Improvement, 2016).

6.1.3.4 Hypothesis 4 - *Hospital Teams with a written oral care protocol will have reduced risk of incidence of SAP compared to those that do not have a written oral care protocol.*

Poor oral and dental hygiene have been identified as potential risk factors for SAP (Bevan, 2015) and lack of oral care has been identified as a significant issue by people affected by stroke (Eltringham et al., 2019b). UK Clinical Guidelines recommend people with stroke, especially those who have difficulty swallowing or are tube fed, should have mouth care at least 3 times a day and staff should be trained in assessment of oral hygiene and selection of appropriate oral hygiene and cleaning agents, and provision of oral care routines. Latest European swallowing guidelines suggest oral health interventions should be considered in stroke patients.

6.1.4 Primary Outcome

The primary outcome was association with stroke-associated pneumonia.

6.1.5 Overview of Study design

A mixed mode survey design comprising of a self-administered electronic survey with a secondary option of a postal survey. The sample frame was Routinely Admitting, and Non-Routinely Admitting Acute Stroke Hospital Teams registered on the Sentinel Stroke National Audit Programme (SSNAP) register. The survey population was Speech and Language Therapy (SLT) Clinical Leads for Acute Stroke in Hyper/Acute Hospital Stroke Units in England and Wales. The total survey population were surveyed. Survey participants were asked to respond about practice on behalf of the Stroke Unit rather than as an individual practitioner.

6.1.6 Sampling plan

Hospital teams were included if they were registered on the SSNAP register for October-December 2019 and had sufficient records/data to report and were an active Hyper/Acute Stroke Unit. One hundred and sixty-six hospital teams were included after exclusions. The SLT Clinical Lead for Acute Stroke or the most appropriate person was identified in each team to complete the survey on behalf of their Stroke Unit. A distribution list with their name and email address was created.

6.1.7 Response rate

The response rate was calculated as the number of completed surveys (1 survey per Hospital Team) divided by the survey population (N=166) multiplied by 100 to express a percentage.

6.1.8 Recruitment Process and access to the questionnaire

Participants were directly contacted by email with an invitation letter, participant information sheet and provided a web link to the survey. A paper-based survey to be returned by a pre-paid stamped address envelope was offered on the last email reminder for those who had not already completed the web-based survey. The survey was a closed survey in that the hyperlink to the survey was only sent to the identified SLT Clinical Lead for Acute Stroke as only one response was requested from each hospital team. No participants requested a paper copy of the survey.

6.1.9 Survey administration

The electronic survey was created using Qualtrics survey software and responses were automatically captured on the Qualtrics platform. Completed

survey responses were exported from Qualtrics to SPSS software for statistical analysis.

The survey was distributed on 2/9/2020. The closing date for the survey was 2/10/2020. The hyperlink remained active for a few days after the closing date to allow for any late responders due to the COVID pandemic.

6.1.10 Statistical analyses

Only completed surveys were analysed. The survey data were analysed using descriptive and inferential statistics. Descriptive statistics included analysis of categorical and continuous data. Descriptive statistics of categorical variables were frequency analysis i.e. percentage of the different categories within each variable. For example, proportion of Hospital Teams that are Routinely Admitting Teams and Non-Routinely Admitting Acute Teams. Categorical data were visualised with bar and pie charts. The evaluation method for continuous data (incidence of pneumonia) were mean and standard deviation to evaluate the dispersion of pneumonia incidence across the hospital teams and visualised using histograms.

Inferential statistics (linear regression analysis) was used to test the hypotheses and explore if there is an association between the dependent variable (incidence of stroke-associated pneumonia) and independent binary variables: 1. Hospital Teams that use Water only dysphagia screening protocols (DSP) versus Hospital Teams that use water and other consistencies DSPs, 2. Hospital teams that use written guidelines for the first specialist clinical bedside swallow assessment versus Hospital teams that do not use written guidelines for the first specialist swallow assessment, 3. Hospital Teams that insert Nasogastric Tubes (NGTs) overnight compared to Hospital Teams that do not insert NGTs overnight and 4. Hospital Teams with a written oral care protocol versus those do not have a written oral care protocol. Linear regression analysis

was visualised using Model Summary tables with Coefficients and 95% Confidence Intervals. The type of analysis for each variable is shown in Table 6.1.

6.1.11 Data sets

Data from the Sentinel Stroke National Audit Programme registry were used (www.strokeaudit.org). Data included administration of antibiotics for a new clinical diagnosis of pneumonia in the first 7 days after admission (Patient Centred Post 72-hour data) and Key indicators 4.5 Percentage of applicable patients who were given a swallow screen within 4h of clock start and 4.6 Percentage of applicable patients who were given a formal swallow assessment within 72h of clock start (Team Centred results). 2019 quarterly data were used to create an annual 2019 data set.

6.1.12 Method for analysing the data for incidence of stroke-associated pneumonia

Stroke-associated pneumonia (SAP) was defined as the administration of antibiotics for a new clinical diagnosis of pneumonia in the first 7 days after admission as determined by the treating physician. SSNAP Patient Centred Post 72-hour quarterly data for Antibiotics for newly acquired pneumonia in the first 7 days from clock start were used to calculate an annual 2019 pneumonia percentage for each team to measure the dispersion of pneumonia incidence across the teams.

6.1.13 Missing data methodology

A forced response was used to avoid participants skipping questions to prevent missing data.

A set of rules were agreed with how to deal with the possibility than one survey was completed on behalf of more than one team e.g. the Routinely Admitting Team (RAT) and Non-Routinely Admitting Team (N-RAT) in the same NHS Trust, or more than one response was submitted for the same team.

Participants were asked to complete 2 separate surveys if they were responsible for more than one team. If only one survey was completed the researcher would confirm that the person completing the survey was the most appropriate person for both teams and ask if the responses would be the same or different for both teams. If the person was not the most appropriate person, the researcher would request the survey be forwarded to the most appropriate person for the other team. If the person confirmed they were the most appropriate person and that their responses would be the same for both teams the researcher would impute the missing data for the second team and record as two responses.

The potential for more than one response to be submitted for a hospital team was minimised by only sending the link to the named person. However, there was the possibility than the role of SLT Clinical Lead may be shared within a team.

Firstly, only completed screens were included. Secondly the researcher confirmed the person completing the survey was the correct person to do so. Finally, the first submission was included.

6.1.14 Sensitivity analysis

Sensitivity analysis was undertaken to understand how certain values contribute to the overall uncertainty of the model. For example, the impact of a lower-than-average response rate from a particular Strategic Clinical Network (SCN) region

or the latest SSNAP annual data which includes data for the Covid-19 period compared to 2019 data (pre Covid-19).

6.1.15 Appendix - Appendix F Published electronic version of the survey “Dysphagia Screening, Assessment and Management in Acute Stroke” 2/9/2020.

Table 6.1 – Proposed analysis for each variable

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
Hospital Team	Survey Question #3 Please type the name of your hospital and select from the drop-down menu. SSNAP 2019 Team Centred 72-hour cohort data	1 = Routinely Admitting Team 2 = Non-Routinely Admitting Team	Categorical – Nominal - dichotomous	Descriptive statistics (frequencies) - Proportion of completed surveys for Routinely Admitting Team and Non-Routinely Admitting Acute Teams by SCN Region	Table
Written Dysphagia Screening Protocol	Survey Question #4 Does your stroke unit use a written dysphagia screening protocol (DSP)?	1 = Yes 2 = No	Categorical – Nominal - dichotomous	Descriptive statistics (frequencies) - Proportion answering yes or no	Bar chart
Standardised Dysphagia Screen	Survey Question # 5 Is the dysphagia screen a screen that was developed by your hospital or a published dysphagia screen?	1= Hospital Dysphagia Screen 2= Published Dysphagia Screen	Categorical – Nominal - dichotomous	Descriptive statistics (frequencies) - Proportion by selected choice	Bar chart

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
	Survey Question #7 Which published dysphagia screen is used?	Free text	Categorical - Nominal	Descriptive statistics (frequencies) – Proportion by named screen	Bar Chart
Person completing the screen	Survey Question #6 Is it mandatory that the person carrying out the dysphagia screen has been trained to use the dysphagia screening protocol?	1= Yes 2= No	Categorical - Nominal - dichotomous	Descriptive statistics (frequencies) - Proportion answering yes or no	Bar chart
	Survey Question #13 Which healthcare professional typically carries out the dysphagia screen? Please specify if more than one healthcare professional group is involved.	1= Stroke Nurse Specialist 2= Registered Nurse 3= Nursing Associate/Apprentice 4= Non-registered staff 5 = Other	Categorical - Nominal	Descriptive statistics (frequencies) – Proportion by selected choice	Pie chart/Free text

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
Components of the screen	Survey Question #8 Are the following involved in the dysphagia screening protocol?	1= Indirect Swallow Test 2= Oro-motor test 3= Indirect Swallow Test AND Oro-motor test 4 = Neither of the above	Categorical - Nominal	Descriptive statistics (frequencies) – Proportion by selected choice	Bar chart
	Survey Question #9 Does the dysphagia screening protocol only use water (Level 0 Thin Fluids) i.e. 100% water? SSNAP 2019 Patient Centred Post 72hr cohort data prescription of antibiotics for a newly diagnosed pneumonia	1= Yes 2= No SPSS Recoded (dummy variables) 0=Yes 1=No	Categorical – Nominal - dichotomous Dependent variable – outcome - incidence of SAP Independent variable – predictor – Water only DSPs versus water and other	Descriptive statistics (frequencies) - Proportion answering yes or no AND Inferential statistics (Linear Regression) Null hypothesis – There is no difference in incidence of pneumonia using a dysphagia screen that uses 100% water compared to	Bar chart Model Summary Table with coefficients and 95% Confidence Intervals

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
			consistencies DSPs	water and other consistencies	
	Survey Question #10 What is the maximum amount of water given? Please indicate the maximum amount in millilitres (mls).	1=5, 2=10, 3=15, 4=20, 5=25, 6=50, 7=100, 8=150, 9=200	Categorical Ordinal	Descriptive statistics (frequencies)- proportion by selected choice	Bar chart
	Survey Question #11 Which International Dysphagia Diet Standardisation Initiative (IDDSI) levels are included in the dysphagia screening protocol?	1= Level 0 Thin, 2= Level 1 Slightly Thick, 3=Level 2 Mildly Thick, 4=Level 3 Moderately Thick, 5=Level 4 Puree, 6=Level 5 Minced and Moist, 7=Level 6 Soft & Bite Size, 8=Level 7 Regular Easy to Chew, 9=Level 7 Regular	Categorical – Ordinal	Descriptive statistics (frequencies) - Proportion by selected choice	Bar chart
	Survey Question #12 Which IDDSI level consistency do you screen with first?	1= Level 0 Thin, 2= Level 1 Slightly Thick, 3=Level 2 Mildly Thick, 4=Level 3 Moderately Thick, 5=Level 4 Puree, 6=Level 5 Minced and Moist, 7=Level 6 Soft & Bite Size, 8=Level 7	Categorical – Ordinal	Descriptive statistics (frequencies) - Proportion by selected choice	Bar chart

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
		Regular Easy to Chew, 9=Level 7 Regular			
Delays in dysphagia screening	Survey Question #14 Below is a list of reasons for delays in stroke patients being screened for dysphagia. How applicable are each of these reasons for delays in stroke patients being screened for dysphagia in your stroke unit?	1=Strongly applicable 2=Somewhat applicable 3=Somewhat less applicable 4=Strongly not applicable	Categorical – Nominal	Descriptive statistics - Likert Scale	Bar chart/Free text
Referral for a specialist swallow assessment	Survey Question #15 If the dysphagia screen identifies a dysphagia, is the patient referred for a clinical (bedside) swallowing assessment carried out by an appropriately trained healthcare professional?	1=Yes 2=No	Categorical – Nominal - dichotomous	Descriptive statistics (frequencies) - Proportion answering yes or no	Bar chart

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
	Survey Question #16 If the patient is not referred for a specialist clinical (bedside) swallowing assessment which health professional group continues to review the patient's swallowing problem after the dysphagia screen?	1= Stroke Nurse 2= Registered Nurse 3= Nursing Associate/Apprentice 4= Non-registered staff 5= Other	Categorical – Nominal	Descriptive statistics (frequencies) – Proportion by selected choice	Pie chart/Free text
Person completing the specialist swallow assessment	Survey Question #17 Which healthcare professional typically carries out the clinical (bedside) swallowing assessment?	1= Speech and Language Therapist 2= Not a SLT but an autonomous Health Professional trained at Specialist Level (as defined by the Inter-Professional Dysphagia Framework)	Categorical - Nominal	Descriptive statistics (frequencies) - Proportion by selected choice	Pie chart
Specialist swallow assessment	Survey Question #18 Does the stroke unit use a published dysphagia assessment for the clinical	1=Yes 2=No	Categorical – Nominal - dichotomous	Descriptive statistics (frequencies) – Proportion answering yes or no	Bar chart

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
	(bedside) swallowing assessment?				
	Survey Question #19 Please state what published assessment is used e.g. The MANN Assessment of Swallowing Ability (MASA).	Free text		Free text	
	Survey Question #20 Do you use written guidelines about what should be included in a clinical (bedside) swallowing swallow assessment? SSNAP 2019 Patient Centred Post 72hr cohort data prescription of	1=Yes – The Mann Assessment of Swallowing Ability 2 = Yes – Not the MANN but other written guidelines 3=No SPSS Recoded (dummy) variables 0=Yes 1=No	Categorical – Nominal AND Dependent variable – outcome - incidence of SAP Independent variable –	Descriptive statistics (frequencies) – Proportion by selected choice AND Inferential statistics (Linear Regression) Null hypothesis – Using written guidelines for the first specialist	Bar chart Model Summary Table with coefficients and 95% Confidence Intervals

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
	antibiotics for a newly diagnosed pneumonia		predictor – Written guidelines (versus clinical reasoning and hypothesis generation)	swallow assessment will not be associated with incidence of pneumonia	
Components of the specialist swallow assessment	Survey Question #21 In your Stroke Unit, what does the first clinical (bedside) swallow assessment typically involve?	1= PMH, 2= HPC, 3= Assessment of cognitive-communication status, 4= Assessment of respiratory status, 5= Cranial Nerve examination, 6=Cough reflex testing, 7= Assessment with oral intake 8= Assessment with postural strategies, 9= Assessment with swallowing manoeuvres, 10= Other	Categorical – Nominal	Descriptive statistics (frequencies) – Proportion by selected choice	Bar chart/Free text
	Survey Question #22 What International Dysphagia Diet	1=Level 0 Thin, 2= Level 1 Slightly Thick, 3= Level 2 Mildly Thick, 4=Level 3 Moderately	Categorical – Ordinal	Descriptive statistics (frequencies) -	Bar chart

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
	Standardisation Initiative (IDDSI) levels are typically included in the first clinical (bedside) swallow assessment?	Thick, 5= Level 4 Puree, 6=Level 5 Minced and Moist, 7=Level 6 Soft & Bite Sized, 8= Level 7 Easy to Chew, 9=Level 7 Regular		Proportion by selected choice	
	Survey Question #23 Please describe what postural techniques are assessed? Examples include chin-down posture, chin-up posture, head rotation (turn to side) and head tilt. These examples are not exhaustive.	Free text		Free text	
	Survey Question #24 Please describe what swallowing manouevres are assessed? Examples of include effortful swallow, Mendelsohn manoeuvre, supraglottic swallow and	Free text		Free text	

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
	super-supraglottic swallow. These examples are not exhaustive.				
Delays in specialist assessment	Survey Question #25 Below is a list of reasons for delays in stroke patients receiving a clinical (bedside) swallowing assessment. How applicable are each of these reasons for delays in stroke patients receiving a clinical swallowing assessment in your stroke unit?	1=Strongly applicable 2=Somewhat applicable 3=Somewhat less applicable 4=Strongly not applicable	Categorical – Nominal	Descriptive statistics - Likert Scale	Bar chart/Free text
Instrumental Swallowing Assessments	Survey Question #26 Does your stroke unit have access to the following instrumental assessments of swallowing?	1= Videofluoroscopy (VFS) 2= Fibreoptic Endoscopic Evaluation of Swallowing (FEES) 3=Neither VFS or FEES 4=Both VFS and FEES	Categorical – Nominal	Descriptive statistics (frequencies) – Proportion by selected choice	Pie Chart

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
	Survey Question #27 For those patients where it is clinically indicated, would your stroke unit routinely use Videofluoroscopy within the first 7 days of a patient's admission? Survey Question #28 For those patients where it is clinically indicated, would your stroke unit routinely use FEES within the first 7 days of a patient's admission? Survey Question #29 For those patients where it is clinically indicated, would your stroke unit routinely use these assessments within the first 7 days of a patient's admission?	1=Yes 2=No	Categorical – Nominal - dichotomous	Descriptive statistics (frequencies) - Proportion answering yes or no	Bar Chart

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
Management	Survey Question #30 During the first 7 days of a stroke patient's admission, what treatment options are typically recommended on your Stroke Unit?	1= Diet and fluids modification, 2= Frazier Water Protocol, 3= Swallowing Manoeuvres, 4= Postural Techniques, 5= Sensory stimulation, 6= Tube feeding, 7=Oro-motor exercises, 8 =Pharmacological Management, 9=Electrical stimulation, 10= Biofeedback, 11= Other	Categorical - Nominal	Descriptive statistics (frequencies) – Proportion by selected choice	Bar chart/Free text
NGT Protocol	Survey Question #31 Does your stroke unit have a written nasogastric tube (NGT) feeding protocol?	1=Yes 2=No	Categorical – Nominal - dichotomous	Descriptive statistics (frequencies) - Proportion answering yes or no	Bar chart
	Survey Question #35 Does your stroke unit have a written protocol for the maximum number of times the NGT can be inserted?	1=Yes 2=No	Categorical – Nominal - dichotomous	Descriptive statistics (frequencies) - Proportion answering yes or no	Bar chart

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
Time from decision to non-orally feed and feeding by NGT	Survey Question #32 In patients who are unable to maintain adequate nutrition and fluids orally, please indicate typically the number of hours from when the decision is taken to non-orally feed and the beginning of feeding by an NGT?	1=< 6 hours 2=≥ 6 - < 12 hours 3=≥ 12 - < 24 hours 4=≥ 24 - < 48 hours	Categorical - Nominal	Descriptive statistics (frequencies) - Proportion by selected choice	Bar chart
Confirmation of position of NGT	Survey Question #33 How does your stroke unit check the position of the NGT before starting feeding?	1= pH testing of NGT aspirate, 2= Chest radiography if no aspirate obtained or pH above recommended level, 3= Routinely perform chest radiography, 4= Other	Categorical - Nominal	Descriptive statistics (frequencies) - Proportion by selected choice	Pie Chart/Free text
Management strategies	Survey Question #34 In cases of inadvertent NGT removal, does your stroke unit typically use any	1= Mittens, 2= Nasal retention device, 3= 1:1 staff: patient supervision, 4=Other	Categorical - Nominal	Descriptive statistics (frequencies) - Proportion by selected choice	Pie Chart/Free text

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
	of the following management strategies?				
Maximum number of NGTs	Survey Question #36 In case of inadvertent NGT removal, what is the maximum number of times reinsertion of the NGT is attempted in any patient?	1=Once, 2= Twice, 3= Three times, 4= If more than three, please state how many	Categorical – Ordinal	Descriptive statistics (frequencies) - Proportion by selected choice	Pie Chart/Free text
Overnight NGT insertion	Survey Question #37 Are NGTs inserted overnight? SSNAP 2019 Patient Centred Post 72hr cohort data prescription of antibiotics for a newly diagnosed pneumonia	1=Yes 2=No SPSS Recoded (dummy) variables 0=Yes 1=No	Categorical – Nominal – dichotomous Dependent variable – outcome - incidence of SAP Independent variable –	Descriptive statistics (frequencies) - Proportion answering yes or no AND Inferential statistics (Linear Regression) Hypothesis – Hospital Teams that insert NGTs overnight have	Bar chart Model Summary Table with coefficients and 95% Confidence Intervals

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
			predictor – Insertion of NGT overnight	increased risk of SAP compared to Hospital Teams that do not insert NGTs overnight.	
Positioning during NGT feeding	Survey Question #38 Where 0 degrees is lying flat and 45 degrees is sat upright, what is the standard position in which the patient is positioned during NGT feeding?	1=0 degrees 2= > 0 - < 30 degrees 3= ≥ 30 - < 45 degrees 4= 45 degrees 5= Other (please state)	Categorical - Ordinal	Descriptive statistics (frequencies) - Proportion by selected choice	Bar chart/Free text
Oral Care Protocol	Survey Question #39 Does your stroke unit have a written oral care protocol?	1=Yes 2=No SPSS Recoded (dummy) variables 0=Yes 1=No	Categorical – Nominal – dichotomous Dependent variable – outcome - incidence of SAP	Descriptive statistics (frequencies) - Proportion answering yes or no AND Inferential statistics (Regression) Hypothesis - Hospital Teams with	Bar chart Model Summary Table with coefficients and 95%

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
			Independent variable – predictor – written oral care protocol	a written oral care protocol will have reduced rates of incidence of SAP compared to those that do not have a written oral care protocol	Confidence Intervals
	Survey question #40 Is this protocol a hospital oral care protocol or a specific protocol written for the oral care of stroke patients on your unit?	1=Hospital oral care protocol, 2= Stroke oral care protocol	Categorical – Nominal - dichotomous	Descriptive statistics (frequencies) – Proportion by selected choice	Bar chart
Oral care provision in H/ASU	Survey question #41 Are there differences in oral care provision for patients in the hyper/acute stroke unit compared to those	1=Yes 2=No	Categorical – Nominal - dichotomous	Descriptive statistics (frequencies) – Proportion answering yes or no	Bar chart

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
	patients in other parts of the stroke pathway?				
	Survey question #42 How is oral care provision in the hyper/acute stroke unit different to that provided post-acute phase stroke?	Free text		Free text	
Oral care provision for dysphagic patients	Survey question #43 Are there differences in oral care provision for patients with dysphagia?	1=Yes 2=No	Categorical – Nominal – dichotomous	Descriptive statistics (frequencies) – Proportion answering yes or no	Bar chart
	Survey question #44 If yes, please describe what differences there are in oral care provision for people with dysphagia compared to the provision	Free text		Free text	

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
	for those people without dysphagia.				
Frequency of oral care for dysphagia patients	Survey question #45 How often each day is mouth care typically provided to people with dysphagia on the stroke unit?	1=Once, 2= Twice, 3= Three times, 4= Other please state	Categorical – Ordinal	Descriptive statistics (frequencies) - Proportion by selected choice	Pie Chart/Free text
Staff responsible for oral care	Survey question #46 Which staff group typically provide oral care? Please indicate if more than one group provide oral care.	1=Registered Nurse, 2= Nursing Associate or Nursing Apprentice, 3= Nonregistered staff e.g. clinical support worker and healthcare assistants, 4= SLT, 5= Occupational Therapist 6= Other - please state	Categorical – Nominal	Descriptive statistics (frequencies) – Proportion by selected choice	Pie chart/Free text

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
Training	Survey question #47 Do staff receive training in oral care?	1=Yes, 2=No	Categorical – Nominal – dichotomous	Descriptive statistics (frequencies) – Proportion answering yes or no	Bar chart
	Survey question #48 What type of training do staff receive?	1= Ward based training, 2= Classroom based training, 3= Online training, 4= Other - please describe	Categorical – Nominal	Descriptive statistics (frequencies) – Proportion by selected choice	Pie chart/Free text
	Survey question #49 Is the training staff receive specific to the oral care of stroke patients?	1=Yes, 2=No	Categorical – Nominal – dichotomous	Descriptive statistics (frequencies) – Proportion answering yes or no	Bar chart
Components of oral care	Survey question #50 What does oral care typically involve on the stroke unit?	1=Brushing of teeth and cleaning of gums with toothpaste 2= Brushing of teeth and cleaning of gums with chlorhexidine dental gel	Categorical – Nominal	Descriptive statistics (frequencies) – Proportion answering yes or no	Bar chart/Free text

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
		3= Brushing of teeth and cleaning of gums using an electric toothbrush 4= Brushing of teeth and cleaning of gums using a suction toothbrush 5= Brushing of teeth and cleaning of gums with a manual toothbrush 6= Removal of excess secretions 7= Removal of dentures overnight 8= Brushing of dentures with water 9= Brushing of dentures and cleaning with soap 10= Brushing of dentures and cleaning with toothpaste			

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
		11= Brushing of dentures and cleaning with chlorhexidine dental gel 12= Soaking of dentures overnight in dental cleaning solution 13= Soaking of dentures overnight in water 14= Application of lip balm 15= Other - please describe			
Variations in practice	Survey question #51 The following question gives you the opportunity to tell us about any other variations in dysphagia screening, assessment and management during the first 7 days of a patient's admission to your stroke unit.	Free text		Free text	

Variable	Data Source (s)	Values	Type of variable	Analysis approach	Methods for summarising data
Sharing of protocols	Survey question #52 Please let us know if you would be happy to share your Trust protocols relating to the screening, assessment and management of stroke patients with dysphagia.	1= Yes 2= No	Categorical – Nominal – dichotomous	Descriptive statistics (frequencies) – Proportion answering yes or no	Bar chart

6.2 Are differences in dysphagia assessment, oral care provision or nasogastric tube insertion associated with stroke-associated pneumonia? A nationwide survey linked to national stroke registry data.

Eltringham, S.A., Bray, B.D., Smith C.J., Pownall S., Sage K. 'Are Differences in Dysphagia Assessment, Oral Care Provision, or Nasogastric Tube Insertion Associated with Stroke-Associated Pneumonia? A Nationwide Survey Linked to National Stroke Registry Data.' Cerebrovasc Dis. 2021 Dec 16:1-8. doi: 10.1159/000519903. Epub ahead of print. PMID: 34915473

6.2.1 Introduction

Stroke-associated pneumonia (SAP) is a frequent complication in acute stroke and a significant predictor of mortality (Westendorp et al., 2011). Dysphagia is a main risk factor and occurs in 37–78% of acute stroke patients (Martino et al., 2005). The drive to decrease this risk has resulted in standards of dysphagia care around the world, and screening and specialist swallow assessment is included in the auditing process for hospital stroke units (Dziewas et al., 2021a).

Early detection of dysphagia is recommended (Bray et al., 2017). The UK Guidelines recommend a validated dysphagia screen (ISWP, 2016b). In practice, a range of dysphagia screening protocols (DSPs) are used (Eltringham et al., 2018). The clinical swallowing assessment (usually undertaken by speech and language pathologists (SLP)) also shows a high degree of variability (McAllister et al., 2016). The level of detail about dysphagia management during the first 72 h of admission after stroke is limited (Eltringham et al., 2018).

The aim of this study was to use survey data to gain a greater understanding of dysphagia assessment and management practice and other related clinical processes specifically oral care and NGT feeding during the first 7 days of hospital admission. Our objectives were to reveal variations in practice in

hospital stroke units who also participated in a large national audit registry in order to use our survey data alongside audit data to estimate associations with SAP.

6.2.2 Methods

6.2.2.1 Study Design and Data Source

A national, cross-sectional survey of SLP Clinical Leads in Acute Stroke was undertaken. The sample frame used hospital stroke units registered with the Sentinel Stroke National Audit Programme (SSNAP), the national register of stroke in England and Wales. Hospital Teams were included if they were registered during October–December 2019, had sufficient records to report, and were actively admitting stroke patients. One hundred and sixty-six teams were included. SAP was defined as the administration of antibiotics for a new clinical diagnosis of pneumonia in the first 7 days after admission (Bray et al., 2017). Data from the survey were linked to SSNAP Hospital Level Patient Centred Post-72-h data. Quarterly data from 2019 were used to create a January–December annual data set.

6.2.2.2 Development and Pretesting of the Survey

A tailored survey design underpinned by social exchange theory was used (Dillman et al., 2014). The topics and question objectives were identified from a series of studies (Eltringham et al., 2018; Eltringham et al., 2019a; Eltringham et al., 2019b; Eltringham et al., 2020). The survey was pretested before fielding the questionnaire to the target population. The definitive version of the survey included 51 questions grouped into 4 topic areas: (a) dysphagia screening, (b) specialist swallowing assessments and management, (c) NGT feeding, and (d) oral care processes.

6.2.2.3 Recruitment Process and Description of the Sample

The survey was a non-open survey using a hyperlink sent only to the SLP Clinical Lead for Acute Stroke. These people were identified through the research teams' professional networks. The respondent answered the survey on behalf of their stroke unit.

6.2.2.4 Survey Administration

The hyperlink to the e-survey was sent through email which opened to the survey web page. Survey responses were captured automatically on the Qualtrics survey platform. The survey was opened on September 2, 2020, for 1 month. The hyperlink remained active after the intended closing date to allow for any late responders due to the second wave of the COVID-19 pandemic. Only completed surveys were included. The CHERRIES checklist (Eysenbach, 2004) was used to ensure complete description of the survey methodology (shown in online suppl. Table 1; for all online suppl. material, see www.karger.com/doi/10.1159/000519903).

6.2.2.5 Statistical Analysis

The statistical analysis plan was registered on ClinicalTrials. gov (Identifier: NCT04779710). Completed survey responses were exported to SPSS for Windows (Version 26.0) predictive analytics software for analysis. Descriptive statistics were used for categorical and continuous data. A simple linear regression analysis using a coefficient model and 95% confidence intervals was used to explore associations between the dependent variable (incidence of SAP) and the independent binary variables.

Sensitivity analysis was undertaken to understand how certain values may contribute to the overall uncertainty of the statistical model. First, the impact of

lower-than-average response rates from a small group of regions was explored. Second, the latest SSNAP annual data (April 19/March 20) were used to explore the possible confounding effect of the beginning of the global COVID-19 pandemic. Finally, all 4 factors were grouped together to run a multivariable model to see what the combined effect would be on the independent variables.

6.2.3 Results

One hundred and thirteen completed surveys were included in the analysis. The completeness rate was 68.1%. The overall incidence of SAP was 9.26% (SD 5.11). The characteristics of the cohort are shown in Table 6.2.

6.2.3.1 Dysphagia Screening Protocols

One hundred and eight teams (95.6%) used a written DSP. In hospital teams who used a written DSP, 97.2% had mandatory training for the person conducting the screen. Stroke Nurse Specialists (SNSs) and Registered Nurses (RNs) most frequently carried out the screen. Some units described different models of screening which included SNSs trained to Specialist Level on the Inter Professional Dysphagia Framework (IDF) (Boaden and Davis, 2006) to carry out the specialist swallow assessment on admission; SNSs and RNs within the same unit trained to different competency levels to screen with a water and multiple consistency screen; and a 2-tier screening process where a water-only screen was undertaken in Emergency Department, and depending on the outcome, the patient was screened more comprehensively on the Stroke Unit. Other models included patients receiving up to 3 swallow screens in the first 24 h.

Table 6.2 Demographic characteristics by region

Values are numbers (percentages) unless otherwise stated

Region	RAT Responses (% RR by region)	N-RAT Responses (% RR by region)	Total Responses (% RR by region)	Mean (SD) SAP incidence as % of all stroke admissions
London	5 (62.5)	15 (75.0)	20 (71.4)	10.89 (6.8)
East Midlands	7 (100.0)	0 (n/a)	7 (100.0)	6.05 (3.3)
East of England	11 (78.6)	0 (n/a)	11 (73.3)	8.74 (5.7)
West Midlands	9 (69.2)	0 (n/a)	9 (64.2)	8.75 (4.9)
GM & Cheshire	1(33.3)	2 (33.3)	3 (33.3)	8.91(3.5)
North West Coast	10 (83.3)	1 (50)	11 (78.6)	8.43 (6.0)
North of England	6 (75.0)	3 (75.0)	9 (75.0)	11.87 (5.4)
Yorks & Humber	5 (55.6)	4 (80.0)	9 (64.3)	7.89 (3.3)
South East	6 (54.5)	2 (100.0)	8 (61.5)	11.10 (4.0)
South West	14 (100.0)	0 (n/a)	14 (100.0)	8.68 (4.1)
Thames Valley	1 (25.0)	0 (n/a)	1 (25.0)	9.56 (.)
Wessex	6 (85.7)	0 (n/a)	6 (85.7)	10.77 (4.5)
Wales	5 (41.7)	0 (0)	5 (33.3)	6.04 (1.4)
Total	86 (70.5)	27 (61.4)	113 (68.1)	9.26 (5.1)

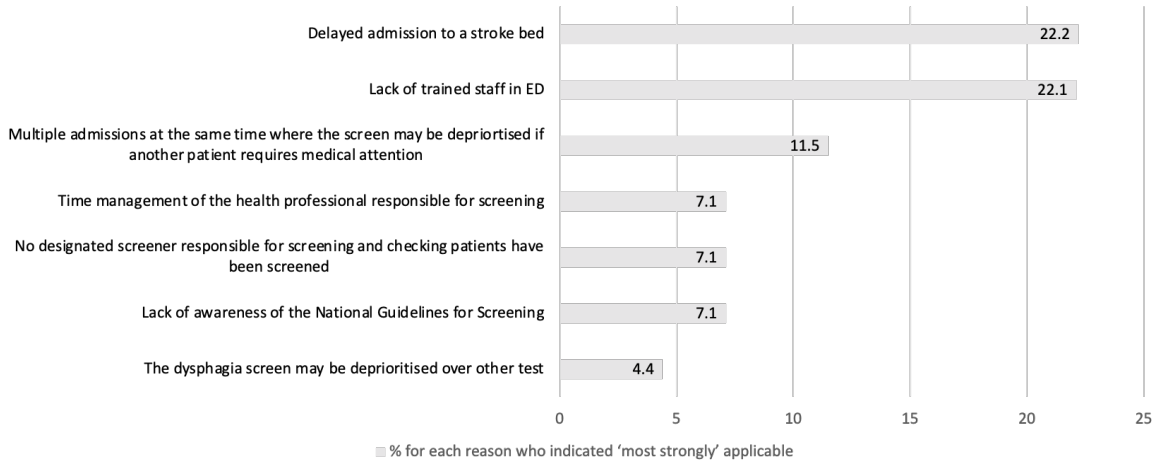
RAT = Routinely Admitting Team, N-RAT = Non-routinely Admitting Acute Team*, RR = Response rate, SD = Standard Deviation, SAP = Stroke-Associated Pneumonia

*Non-routinely admitting acute teams are teams which do not generally admit stroke patients directly but continue to provide care in an acute setting when patients have been transferred from their place of initial treatment.

Ten teams used published dysphagia screens. Eight different screens were used (shown in online suppl. Fig. 1). One response was excluded due to an incorrect response. One hundred and two hospital teams (90.3%) used a locally developed DSP. Ninety-five percent involved either an indirect swallow test or an indirect swallow test and oro-motor test. Fifty-three (52%) of the 102 teams that used a locally developed DSP used a water-only DSP compared to a multiconsistency screen. The maximum amount of water ranged from 10 mL to 200 mL. In the 49 teams which used a multiconsistency DSP, International Dysphagia Diet Standardisation Initiative (IDDSI) Level 0 Thin Fluids, Level 4 Pureed, and Level 7 Regular Diet were most frequently used (Initiative IDDSI, 2019). Level 0 was used first by 91.8% (N = 45) of teams compared to 8.2% (N = 4) which began screening oral intake with Level 3 Moderately Thick fluids.

Reasons for delays in patients being screened for dysphagia are shown in Figure 6.1. All teams referred patients to an appropriately trained professional for a clinical swallow assessment if dysphagia was identified.

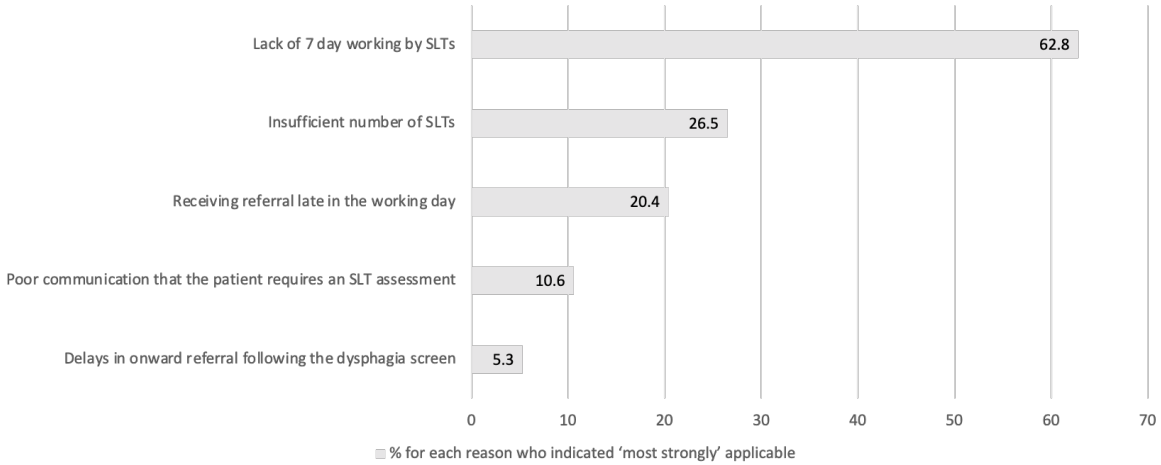
Figure 6.1 Reasons for delays in dysphagia screening



6.2.3.2 Clinical Swallow Assessment

One team used a published clinical swallow assessment: The Mann Assessment of Swallowing Ability (MASA), and 36 teams (32%) used other written guidelines; locally developed guidance was mainly used. Seventy-six out of 102 hospital teams (67.3%) did not use written guidelines. The swallowing assessment involved gathering information about the patient's medical history and presenting condition, assessment of the patient's cognition, communication, and respiratory status, a cranial nerve examination, and assessment with diet and fluids. There was the potential for the full range of the IDDSI levels to be included. Forty-six percent of teams used postural techniques, 35% used swallowing manoeuvres, and 15% used cough reflex testing. Assessment with postural techniques and swallowing manoeuvres was dependent on the patient's physical and cognitive status. Five teams assessed these using videofluoroscopy (VFS) rather than at the patient's bedside. Reasons for delays in patients having a clinical swallow assessment are shown in Figure 6.2.

Figure 6.2 Reasons for delays in specialist swallow assessment



6.2.3.3 Instrumental Swallowing Assessments

One hundred and nine teams (96.5%) had access to instrumental swallowing assessments. Of those who had access to VFS and fibre optic endoscopic evaluation of swallowing (FEES), 15 of the 52 teams (29%) would typically use these assessments if clinically indicated within the first 7 days of admission, compared to 9 of the 56 teams (16.1%) who had access to VFS only. The 1 team that had FEES only would typically use it within the first 7 days if indicated.

6.2.3.4 Treatment Options

Diet and fluid modification (100%), NGT feeding (98%), postural techniques (59%), oro-motor exercises (54%), swallowing manoeuvres (49%), pharmacological management (38%), sensory stimulation (33%), Frazier Free Water Protocol (24%), biofeedback (7%), and electrical stimulation (3%) were options recommended during the first 7 days of a patient's admission.

6.2.3.5 Nasogastric Tube Feeding

One hundred and one hospital teams (89.4%) had a written NGT protocol. Time from decision to non-orally feed and feed by NGT was 43.4% (<6 h), 32.7% (≥6 to < 12 h), 14.2% (≥12 to < 24 h), and 9.7% (≥24 to < 48 h). Sixty-four out of 113 hospital teams (56.6%) inserted NGTs overnight. Confirmation of NGT placement was done by pH testing of the NGT aspirate (74.3%) and chest radiography if no aspirate was obtained or pH was above the recommended level (85.8%). Nineteen teams (16.8%) routinely performed chest radiography before starting feeding.

The standard position for feeding was a minimum of 30°, with 40.7% of teams specifying 45° as the standard. Mittens (94%), nasal bridles (83%), and 1:1 patient staff supervision (64%) were used in cases of inadvertent NGT removal. Responses varied about the maximum number of times the NGT would be reinserted in any patient.

6.2.3.6 Oral Care

Seventy-two (63.7%) of the 113 teams had a written oral care protocol. In 11 (15.3%), the protocol was specifically for stroke patients. Clinical Support Workers and Health Care Assistants, RNs, SLPs, and Nursing Associates or Nursing Apprentices most frequently carried out oral care. In 76 teams (67.3%), staff received training. In 26 (34.2%), training was specific to the oral care of stroke patients. Training included ward-based (53.1%), classroom based (19.5%), and online training (17.7%).

Ninety-five teams (84.1%) did not consider oral care in acute stroke as any different to the oral care in other parts of the stroke pathway. Seventy-one teams (62.8%) did perceive there to be differences in oral care needs and provision for patients with dysphagia which included increased frequency of oral care, patient-specific recommendations, and use of specialist mouth care products and equipment. In patients who were NBM, less frequent oral care was justified because patients were drowsy, and staff worried about risk of aspiration. There was a wide variation in the frequency of oral care (every 1–2 h to once a day). The most frequently used interventions were removal of excess secretions (100%) and brushing of teeth and cleaning of gums with toothpaste (96%) compared to chlorhexidine gel (35%) (shown in online suppl. Fig. 2, 3).

6.2.3.7 Associations between Described Care Processes and SAP

The univariable (shown in online suppl. Table 2) and multivariable (shown in Table 6.3) analyses indicate no evidence of an association in the incidence of SAP when comparing teams who use a water-only hospital DSP compared to teams who use water and other consistencies, nor when comparing teams who use written assessment guidelines for their clinical assessment of swallowing compared to those who did not. Similarly, there was no link between incidence of SAP and whether teams inserted NGTs overnight or teams who did not, nor teams who had a written oral care protocol compared to those who did not.

6.2.3.8 Sensitivity Analysis

Findings were unchanged when using the SSNAP April 19–March 20 Patient Centred Post-72-h cohort data and when the low % respondent regions, GM and Cheshire, Thames Valley, and Wales, were excluded from the model (shown in online suppl. Tables 3, 4).

Table 6.3 Coefficient[a] Multivariable analysis

		Unstandardized Coefficients				95.0% Confidence Interval for B	
Model	Sample	B	Std. Error	t	Sig.	Lower Bound	Upper Bound
Type of DSP Water only (Reference) vs. water and other consistencies.	102	-.688	1.120	-.614	.541	-2.912	1.536
Written guidelines for clinical swallowing assessment Use of written guidelines (Reference) vs. no written guidelines.	102	.671	1.127	.595	.553	-1.567	2.908
Insertion of NGT overnight Overnight NGT insertion (Reference) vs. no overnight NGT insertion.	102	-.505	1.136	-.444	.658	-2.759	1.749
Written oral care protocol Hospitals with a written oral care protocol (Reference) vs. Hospitals without a written oral care protocol.	102	-1.339	1.115	-1.201	.233	-3.551	.873

a. Dependent Variable: Antibiotics for newly acquired pneumonia in the first 7 days from clock start using SSNAP 2019 Patient Centred Post 72h data

6.2.4 Discussion

National registers such as SSNAP allow us to record timings of care processes potentially relevant to SAP by recording actions taken in the first 72 h, important because patients are increasingly susceptible to infection in the first days after stroke. Our research aimed to unpick what we know are a multifactorial and complex set of factors, by revealing variations in organizational practice and find out what if any has an impact on the incidence of SAP. Four care process issues that might contribute to SAP were identified (using a DSP that uses 100% water compared to a DSP that uses water and other consistencies, using written guidelines for the first specialist swallow assessment, insertion of NGTs overnight, and using a written oral care protocol).

We found variation across hospital teams in dysphagia screening, specialist swallow assessment and management, oral care, and NGT care processes during the first 7 days of hospital admission. In this study, clinical equipoise was almost 50:50 when choosing whether to use water-only DSPs or screening protocols which used multiple consistencies. In the absence of comparative studies to determine whether the outcome is better between the different screening regimes, patients with acute stroke should be screened with a formal dysphagia screening test as fast as possible after admission to the hospital using either water or multiple consistency tests (Dziewas et al., 2021a).

Early screening of dysphagia and specialist swallow assessments are associated with reduced risk of SAP (Bray et al., 2017; Al-Khaled et al., 2016; Dhufaigh and Hayes, 2017). Our study identified the most frequently reported reasons for delay. The clinical implication of this finding is that some of the reasons for delay are modifiable and have the potential to contribute to reducing the incidence of SAP. For example, having enough trained staff in Emergency Department to screen patients on admission, improving patient flow to a designated stroke bed, 7-day SLP working, and training SNSs to Specialist

Level on the IDF would potentially lead to patients being assessed by a specialist sooner and thereby reduce risk of patients developing SAP.

This survey provided further information about what is included in the clinical swallow assessment and new knowledge about SLP management options. Our study concurred with McAllister et al. (McAllister et al., 2020) that there are core components in the clinical bedside assessment. We also revealed variances. These differences may arise based on individual patient presentation, development and testing of hypotheses (McAllister et al., 2020), organizational protocols (i.e. use of cough reflex testing), and evidence-based practice (i.e. use of instrumental assessments to inform management). This survey found that less than two-thirds of our sample had a written oral protocol and approximately 90% had a written NGT protocol. There was variation in oral care and NGT processes. There is a continuing paucity of good-quality evidence about oral care interventions in acute stroke (Campbell et al., 2020), and to date, the evidence that NGT placement increases risk of SAP is equivocal (Eltringham et al., 2020). Randomized control trials such as the CHOSEN feasibility trial (Smith et al., 2021a) which is investigating oral healthcare interventions in stroke patients with dysphagia are needed to inform clinical guidelines.

The results of this study did not find evidence of an association between clinical practice patterns and incidence of SAP. The study was robust in survey design, had a high completion rate, and these data were used in combination with data drawn from an established national registry. There are limitations to the survey design used which may prevent the study from detecting any associations between the variables explored here and SAP. There is a possibility of misclassification error although this was minimized by careful design to ensure that the most appropriate person was surveyed in order that the data were as accurate as possible. Another potential threat to validity is the incidence of SAP reported by the National Stroke Audit for the period of analysis. While this is possible, the incidence of SAP has remained stable since the start of the

SSNAP registry in 2013 (mean 8.56, SD 0.28) and is consistent with the wider literature (Hannawi et al., 2013). It is possible that the size of the effect may have been too small to detect, and an effect may have been picked up in a larger group of hospital teams. The authors aimed to minimize other potential limitations, including the possibility of recall bias by employing a tailored survey design and pretesting the survey.

Trying to unpack and identify which factors may contribute to risk of SAP is challenging. Some of the processes such as dysphagia screening and the specialist swallow assessment occur sequentially in a patient's pathway while others (such as implementation of the SLP care plan and oral care) are ubiquitous, underpinning care throughout the whole hospital stay; meanwhile, placement and confirmation of the NGT may be carried out more than once and will happen in a less predictable way based on the patient requirement making it difficult to unpack. Additionally, different professional groups are involved in delivering these care processes. Aoki et al. (Aoki et al., 2016) found that an MDT approach to swallowing reduced incidence of SAP. To understand the difference of this approach, frequencies of professional oral care and instrumental swallowing evaluations before and after team organization were evaluated. Our research identified a potential underuse of instrumental swallowing assessments when clinically indicated during the first 7 days of admission. In a comparative survey of German stroke units (Flader et al., 2017), FEES was more readily available than VFS, with 71% of stroke units having access to FEES. This may be in part due to FEES being a criterion for Stroke Unit accreditation (Dziewas et al., 2021b).

Recommendations for future research might include further exploration of the link between screening methods and SAP and undertake a feasibility trial and randomize patients to 1 of 2 treatment groups: one using a water-only DSP and the second group using water and other consistencies, to assess the relative association of SAP of these 2 screening regimes. Additionally, a larger sample

at both registry and survey level might show associations which this national sample was unable to detect. A European-wide stroke registry and survey might provide a large enough sample to detect important variations if the same methodology were used. Further evaluation of care processes such as SLT management practices, for example, use of limited oral trials for those at risk of aspiration if full amounts are taken orally (Julier and Benfield, 2021), is warranted.

The supplementary material is available in the Appendix G Supplementary material for the survey results (Page 342).

Chapter 7 Discussion

Introduction

This doctoral thesis includes five published papers. Individual discussion sections have been presented in each of these published papers along with the case note review. This chapter is therefore presented in an editorial style. It begins with an overview of the problem addressed and provides a summary of the different study designs that were used as part of the overall programme of research. The challenges of identifying which components of dysphagia assessment and management are associated with risk of stroke-associated pneumonia (SAP) in patients admitted to hospital following acute stroke are discussed. Potential limitations of the research, implications for clinical practice followed by suggestions for future research directions are considered.

7.1 Overview of the problem investigated

This programme of research set out to answer the research question 'How does variation in assessment and management of dysphagia in acute stroke affect the development of stroke-associated pneumonia?' This question was addressed by carrying out a nationwide survey of SLTs in stroke units in England and Wales to collect data about clinical practice patterns. Four care processes were analysed for association with increased risk of SAP by linking survey data with hospital level SSNAP data. These were using a dysphagia screening protocol that uses 100% water versus a multi consistency screen; using written guidelines for the clinical swallowing evaluation; placement of NGTs overnight and using a written oral care protocol.

The pathophysiology of SAP is multifactorial which makes it difficult to unpick which components of dysphagia assessment and management are associated with increased SAP episodes. Firstly, there is a complex interplay between

causal factors: the source of infection, the mechanism for delivery of bacteria to the lungs; and immunosuppression. Potentially stroke severity is also causally implicated. Increased stroke severity may lead to reduced consciousness and impaired postural stability and sitting balance (aspiration risk enhanced); it can be associated with dysphagia (aspiration); and drive immune suppression (enhanced infection susceptibility). Other clinical characteristics such as age, congestive heart failure, diabetes, atrial fibrillation, and degree of disability or dependence are also known SAP risk factors (Hannawi et al., 2013). However, a recent investigation of the variation of SAP incidence in stroke units in England and Wales (Chaves et al., 2022), found patient characteristics only accounted for 5% of the variance. This suggests that the approach to SAP diagnosis and the threshold for administration of antibiotics and other potentially modifiable factors such as clinical processes account for most of the variation observed.

7.2 Overview of the programme of research

This research comprised of two systematic reviews of the literature, a mixed methods study and a quantitative study. The systematic reviews summarised the current evidence related to the research question. The first review identified large variation in how dysphagia is assessed and managed in stroke patients admitted to hospital and found moderate evidence from observational studies that early screening and specialist swallow assessment may reduce the odds of SAP. The second systematic review found that SAP is associated with a range of medical interventions and care processes in stroke patients with dysphagia. The systematic reviews informed the data collection instrument for a case note review from patients who were screened and assessed for dysphagia on admission to hospital and the topic guides for two interview studies. The case note review provided detailed understanding of dysphagia management during the first 72 hours from admission and identified potential reasons for under performance against SSNAP targets for dysphagia assessment, and factors that

may contribute to development of SAP and patient safety. The first interview study with staff involved in the assessment and management of dysphagia identified reasons for delays in dysphagia screening and assessment, lack of standardisation, and variability in resources. The second interview study explored the experiences of stroke patients who had their swallowing assessed during their first 72 hours of admission to hospital and identified what was most relevant from a patient perspective, which included procedural issues and communication to patients. The results of the mixed methods studies were integrated, analysed and interpreted to inform the questions for a national survey sent out to SLT Clinical Leads in Acute Stroke in hyper/acute stroke units (H/ASU) about dysphagia assessment and management practice. The survey questions were grouped into 4 topic areas: (a) dysphagia screening, (b) specialist swallowing assessments and management, (c) NGT feeding and (d) oral care processes. The results of the survey were statistically analysed and linked with data from the SSNAP register to explore variation in organisational practice and associations with SAP.

7.3 Challenges of identifying which components of dysphagia assessment and management in acute stroke are associated with risk of SAP

Early identification of dysphagia is thought to minimise risk of SAP, however despite national clinical guidelines recommending screening patients for dysphagia within 4 hours and assessment by a specialist within 24 hours, the incidence of pneumonia as recorded in national stroke data remained unchanged (Eltringham et al, 2021). Bray et al. identified that risk of SAP was significantly reduced in patients who had a specialist swallowing assessment sooner rather than later, however it is unclear which aspects of the specialist swallowing assessment and subsequent management are associated with risk of SAP. One hypothesis is that patients who are referred for a specialist assessment may have a more severe dysphagia and the outcome of the specialist assessment maintains the status quo i.e. the recommendations

following the dysphagia screen are unchanged, for example, the patient remains Nil by mouth (NBM), and this minimises risk of SAP. In the clinical audit, of the initial 28 patients who had a swallow screen and then a formal swallow assessment, for 15 patients (54%) the recommendations did not change, which could support further investigation of this hypothesis. However, one explanation was that 10 of these assessments (67%) were undertaken by stroke nurses who completed a specialist swallow assessment on admission. For the remaining 13 patients, there was an almost 50:50 split between the recommendations being advanced or downgraded (following the first clinical swallowing assessment). The small sample size of the audit and that it was conducted in a single site means that limited conclusions can be drawn.

It is also possible that other components of the initial swallowing assessment such as the assessment of postural techniques and swallowing manoeuvres and subsequent implementation of these strategies and others treatment options maybe positively associated with minimising risk of infection during the first 7 days of admission. This research revealed that, in addition to dietary and fluid modification, a large proportion (54%) used oro-motor exercises. In a recently updated Cochrane systematic review about swallowing therapy in acute/sub-acute stroke presented at the UK Stroke Forum 2021 (Wilkinson et al., 2021), it was reported that there is increasing evidence to suggest a significant effect for individual treatment interventions in improving swallowing ability, including acupuncture, behavioural interventions and neuromuscular electrical stimulation. However, based on the grade analysis, the quality of evidence was considered low-moderate and the findings could not inform clinical guidelines. Behavioural interventions, which may be compensatory or rehabilitative in nature, were associated with reduced risk of chest infection/pneumonia (OR 0.43 [0.25, 0.74], p=0.002). However, while this systematic review is of clinical interest, it is not directly applicable to the research question due to the emphasis on the rehabilitative nature of these

interventions and participants were recruited with a clinical diagnosis of stroke up to six months of onset.

An alternative hypothesis is that, as part of the specialist swallowing assessment, the importance of oral hygiene in patients with dysphagia as well as safe eating advice may be heightened amongst other members of the MDT. This research identified that speech and language therapists (SLTs) as a professional group frequently provided oral care alongside nursing staff. Oral care is a much-overlooked part of a stroke patient's care with lack of staffing resource, lack of confidence and appropriate tools being cited as reasons for neglect (Lyons et al., 2018). Wide variation in oral care exists with only 11 out of the 72 stroke units who had a written oral care protocol stating this was specifically for stroke patients. In one stroke unit which had a stroke oral care protocol, patients who were NBM or who were on oral trials were placed on a stroke-associated pneumonia care bundle which triggered use of chlorhexidine gel and hourly mouthcare. In contrast, in the audit component of this study, prescription of oral care was not documented, making it unlikely that this element of the stroke care bundle was being implemented effectively.

The second systematic review (Eltringham et al., 2020) identified two studies (Aoki et al., 2016; Gandolfi et al., 2014) which investigated the impact of multidisciplinary management of swallowing in acute stroke. Aoki et al. (2016) found an integrated MDT approach reduced the incidence of SAP, however lacked detail about what the intervention involved. Both studies used either FEES and/or VFSS instrumental assessments and emphasised the cooperation and utilisation of different professionals. In a pre-post comparison study of the implementation of a FEES service on functional outcomes in acute stroke patients (Bax et al., 2014), there was a significant reduction of pneumonia rates in the group that had access to FEES (P .037) and in the FEES group, instrumental assessment was significantly associated with not developing pneumonia (P .026). This research showed that, despite 109 out of 113 teams

(96.5%) having access to either FEES or VFSS, many units did not typically use these assessments when clinically indicated during the first 7 days of admission. The sample size to compare teams who used either VFSS and or FEES or both instrumental assessments compared to those who did not, was too small to analyse for an association with SAP. Future studies about whether instrumental assessment compared to the initial clinical bedside assessment reduces risk of SAP and improves functional outcomes, with a larger sample, is warranted.

7.4 Potential Limitations of the Research

This research exposed variations in dysphagia management practices but found no evidence of an association between the variables examined and incidence of pneumonia. However this does not mean an association does not exist. A limitation of this research is the size of the survey sample which meant that it was possible that there may have been an association between the independent variables explored and SAP, but the size of the effect was too small to detect. The response to the survey was considered desirable (Burns et al., 2008); however there is the potential that, even if all 166 units had responded, this may still have been too small and that a European-wide stroke registry and survey might provide a large enough sample to detect an association if the same methodology was used. An international study including the UK and Europe, while providing a larger sample, may introduce additional challenges, given likely differences in clinical practice patterns and lack of standardisation of data collection.

A further limitation of this research is the retrospective study design and that participants were asked to reflect on clinical practice patterns and protocols. There was the potential for recall bias that a prospective design with more rigourous data collection would minimise. There is also an acknowledgement that some participants may not have felt best placed to answer questions about NGT placement and oral care. However, the interdisciplinary management of

dysphagia meant the SLT Acute Leads were able to source the information, which was confirmed by the survey respondents.

A foundation of this research was the use of SSNAP data. The method for capturing SAP by capturing new antibiotic initiation is not a record of the diagnostic approach or decision-making process by clinicians and may not be representative of the clinical diagnosis of pneumonia. SSNAP only records clinically diagnosed pneumonia that was treated with antibiotics, which is not necessarily the same as “clinical diagnosis of pneumonia” (as some patients with clinically diagnosed pneumonia may not have received antibiotics, for example, in patients with severe stroke and multiple co-morbidities or when approaching end of life and treatment was not considered appropriate). Another potential limitation is how clinicians diagnose SAP. The first systematic review (Eltringham et al., 2018) identified a range of different approaches used. Dependent on how SAP is diagnosed has the potential to impact on antibiotic stewardship, with physicians tending to over-diagnose SAP compared to algorithm-based approaches (Kalra et al., 2016). Use of algorithm diagnosis could result in greater standardisation of SAP diagnosis for clinical practice and research.

7.4.1 Future improvements in SSNAP data collection to help with dysphagia research

Dysphagia and severity of dysphagia is not directly recorded in SSNAP. We can deduce that patients who are recorded as having a comprehensive swallowing assessment, failed the dysphagia screen and/or there were concerns about the safety of the patient’s swallow that initiated a referral for a specialist assessment. However, this may overestimate, or underestimate patients clinically diagnosed with dysphagia. For example, a patient may have ‘failed’ the indirect assessment of a dysphagia screening protocol because of concerns of risk of aspiration due to reduced alertness and referred for a specialist swallow

assessment but, when more alert, was not diagnosed with dysphagia and deemed safe for normal fluids and diet intake. Conversely, a patient may have 'passed' the dysphagia screen and subsequently been re-referred for a specialist assessment because of a deterioration in their status or the dysphagia screen did not screen the patient on a particular consistency which the patient is later referred for as having difficulties with. This also links in with the wide variation in dysphagia screening tools being used and that some tools screen for aspiration risk as opposed to screening for dysphagia.

Future improvements in SSNAP data collection might include the recording of the type of dysphagia screen used (i.e. water only vs. a multi-consistency tool), and dysphagia severity at the time of the specialist swallowing assessment. Dysphagia severity scales are objective measures that can track changes to severity of dysphagia over time, secondary to intervention. Several scales exist for grading the severity of clinical dysphagia based on oral intake, such as the functional oral intake scale (FOIS) (Crary et al., 2005), and the dysphagia severity rating scale (DSRS) (Everton et al., 2020). There is also the Therapy Outcome Measures (TOMS) (Enderby and John, 2015) and the International Dysphagia Diet Standardisation Initiative Functional Diet Scale (Steele et al., 2018), that capture the severity of oropharyngeal dysphagia, as represented by the degree of diet texture restriction recommended for the patient. However, these scales are subjective and there is risk of clinician bias. There are aspiration severity scales such as the Penetration-Aspiration Scale (Rosenbek John, 1996) which are used for measuring aspiration that may be quantified using VFSS or FEES. However, instrumental assessments, particularly VFSS are less likely to be used during the patient's first 72 hours of admission. The lack of consensus about severity scales may prove challenging for the purposes of standardised data collection. There is also an appreciation of the demands placed on SLTs and administrators responsible for submitting data to the SSNAP database and that additional data inputting would place further pressures on an already stretched work force. The priority must be for all stroke

patients to be screened for dysphagia and assessed by a specialist as soon as possible. However, many stroke units already use some of these outcome measures. The collection of these data would benefit future stroke patients by being able to track the impact of dysphagia assessment and management interventions over time and future research by improving standardisation of outcome measures reported.

7.4.2 Auditing care processes

At UK Stroke Forum 2021, Dame Professor Caroline Watkins spoke about how assessment alone cannot achieve better outcomes and questioned whether the SSNAP auditing process was 'missing the mark' by not auditing more of the care. Care processes might include basic factors such as positioning and supporting dependent patients with feeding, and oral care after feeding, as known SAP risk factors (Langmore et al., 1998; Huang et al., 2006). But how can these care processes be meaningfully audited? These types of care processes would be challenging to quantify for audit purposes unless categorised and standardised throughout the UK. Prescription of oral care could be recorded; however, prescription does not guarantee that oral care is being administered. How frequently a patient receives oral care could be accessed from a patient's nursing care record. Although, oral care is not always distinguished from other personal activities of daily living unless there is a specific oral care protocol. This research identified only 64% (72/113) of the stroke units had a written oral care protocol. It also requires professionals to document that oral care has been carried out. In the meantime, the evidence base for oral care interventions is developing (Smith, 2021). However, even if a positive association is not found between oral care intervention and SAP, oral hygiene and a comfortable clean mouth is a basic care requirement.

7.5 Implications for clinical practice

This research has created new knowledge by exposing a wide variation in dysphagia screening practice in acute stroke units in England and Wales. Different methods and tools for evaluating dysphagia were known to exist (Daniels et al., 2012) but this research was unique in systematically exploring these variations in clinical practice. Quantifying these variations is a critical first step in investigating the impact of dysphagia screening practice on post stroke pneumonia. Our research identified most stroke units used locally developed DSPs compared to published protocols and there was an almost 50:50 split between stroke units using a hospital water only DSP compared to a multi-consistency tool. No evidence of an association in incidence of SAP was found between the different screening regimes. This finding is consistent with the ESO-ESSD guideline for the diagnosis and treatment of post stroke dysphagia which recommends a formal dysphagia screening test with either a water-swallow-test or multiple-consistency screen in the absence of any comparative studies to determine which approach is better. A recent Cochrane review (Boaden et al., 2021) was also unable to identify a single tool that could accurately identify aspiration risk associated with dysphagia in acute stroke. The review did identify the best combined water swallow and instrumental test (the Bedside Aspiration test), the best water plus other consistencies tool (the Gugging Swallowing Screen), and the best water only tool (Toronto Bedside Swallowing Screening Test). Caution was recommended in the interpretation of the findings, due to the tests being based on single studies with small sample sizes.

In the absence of comparative studies to determine which dysphagia screen regime is better at minimising SAP risk, there is moderate quality evidence for all patients to be screened for dysphagia before administration of any food or liquid, including oral medication, with a formal dysphagia screening protocol as fast as possible. If dysphagia is identified, a patient should be assessed by a

specialist as soon as possible. This research identified the most frequently identified reasons for delays in dysphagia screening and assessment. The clinical implication of this knowledge is that some of these factors have the potential to be addressed and therefore may contribute to reducing risk of SAP.

This research identified a potential under-use of instrumental swallowing assessments. There is insufficient evidence to recommend the routine use of instrumental assessment for people identified at risk of dysphagia, although the benefits of these assessment are felt to outweigh any associated risk (Dziewas et al., 2021). The ESO-ESSD guideline recommends in addition to the clinical swallowing examination, VFSS or preferentially FEES, should be available. The staff interview study component of this research identified that staff attitudes were a potential barrier to utilisation of FEES as well as availability of staff competent to use the equipment and problems with the equipment. A potential implication of this research is where these resources are available, there should be greater utilisation in patients with post stroke dysphagia if clinically indicated. There is potentially a requirement to raise awareness amongst some staff to promote the benefits of FEES.

This research identified that a substantial proportion of teams did not have a written oral care protocol. Even fewer teams had a stroke-specific oral care protocol, and ninety-five teams (84.1%) did not consider oral care in acute stroke as any different to the oral care in other parts of the pathway. Within a single institution, a range of different oral care practices can exist (Eltringham et al., 2019a). Currently, there are few evidence-based assessment tools and protocols for oral care in stroke patients and national and international guidelines about oral intervention in patients with post stroke dysphagia are based on weak evidence and lack detail about how best to provide intervention. Oral care protocols need to “describe simple preventative measures at each stage in the care pathway combined with early diagnosis and management of significant dental pathology” (Lyons et al., 2018). Further high quality RCTs are

needed to determine which combinations of oral care interventions are most effective to provide evidence to inform standards for best oral care practice.

7.6 Future research directions

Undertaking research which has been identified by people who have been affected by stroke ensures that the research is relevant and reflects the needs and priorities of those affected. Reducing post stoke complications such as pneumonia and what effect diet has on short and long term outcomes are two of the research priorities identified by people affected by stroke and stroke care professionals in research into stroke prevention, diagnosis, pre hospital and hospital care (JLA, 2021).

A role for future trials might include further exploration of the link between screening methods and SAP (Eltringham et al., 2021). There is also a role for trials to investigate the effectiveness of routine use of formal instrumental assessments in acute phase stroke in patients who fail the dysphagia screen, on preventing SAP, particularly in patients with low mHLA-DR expressions (Eltringham et al., 2020). The advantage of FEES compared to VFSS is that FEES can be performed at the patient's bedside, is cost effective and with no radiation exposure it can be repeated if clinically indicated (Eltringham et al., 2018). FEES also has the advantage that it can assess secretion management and the efficacy of clearing mechanisms such as coughing and throat clearing, and pharyngeal sensation (Dziewas et al., 2021). In patients with acute stroke who fail the screen, a feasibility trial could compare whether clinical bedside assessment compared to FEES, reduces risk of SAP and other adverse clinical outcomes. The rating of dysphagia severity using these different assessment methods could also be compared along with the management strategies arising from these assessments.

This research identified that 15% of hospital teams who responded to the survey used cough reflex testing as a complementary assessment to the clinical swallowing assessment. There is insufficient evidence of the efficacy of cough reflex testing to minimise risk of SAP and there is developing research in this area (Trimble et al., 2021). Further robust trials are needed to compare cough reflex testing and the standard clinical bedside swallowing assessment on the different management approaches and impact on post stroke pneumonia.

Further evaluation of the impact of dysphagia management strategies and what effect this has on stroke patient outcomes, such as prescribing modified diet and modified fluids is also warranted (Teuschl et al., 2018). There is also a need to better understand the interdisciplinary management of dysphagia and the delivery of inter-dependent care processes during the first 72 hours/7 days of admission. A platform trial design would allow for evaluation of multiple interventions to be analysed simultaneously. This new type of clinical trial design has the flexibility to drop interventions early and introduce new interventions using interim evaluations and statistical analysis, and for the control arm to be updated during the trial. Platform trials are considered more “diseased focused” (e.g. ‘‘What is the best intervention option for SAP?’’) rather than “intervention focused” (e.g. 2 armed trials) (Park et al., 2020) and would allow evaluation of multiple dysphagia management practices on the development SAP.

There is also a role for further qualitative research to explore in more depth some of these factors at a patient level. An ethnographic study of stroke patients admitted to hospital using structured observation at contrasting times of the day, including weekends, would capture oral care intervention, implementation of specialist swallowing assessment recommendations, positioning for feeding including tube fed patients, and dependency for oral care and feeding. An observation tool, for example, the Mealtime Assessment Scale (MAS) (Pizzorni et al., 2020) that uses the International Classification of Functioning, Disability

and Health (ICF) as a conceptual framework, could be used as part of this structured observation in addition to stroke patient medical records, which would be followed up prospectively for 7 days from admission for the development of stroke-associated pneumonia.

References

Al-Khaled, M., Matthis, C., Binder, A., Mudter, J., Schattschneider, J., Pulkowski, U., Strohmaier, T., Niehoff, T., et al. (2016) 'Dysphagia in Patients with Acute Ischemic Stroke: Early Dysphagia Screening May Reduce Stroke-Related Pneumonia and Improve Stroke Outcomes.' *Cerebrovasc Dis*, 42, (1-2) 2016/04/14, pp. 81-89.

Ali, A. N., Howe, J., Majid, A., Redgrave, J., Pownall, S. and Abdelhafiz, A. H. (2018) 'The economic cost of stroke-associated pneumonia in a UK setting.' *Top Stroke Rehabil*, 25(3), Apr, 2017/11/04, pp. 214-223.

Allmark, P., Boote, J., Chambers, E., Clarke, A., McDonnell, A., Thompson, A. and Tod, A. M. (2009) 'Ethical Issues in the Use of In-Depth Interviews: Literature Review and Discussion.' *Research Ethics*, 5(2), 2021/09/28, pp. 48-54.

Alsumrain, M., Melillo, N., Debari, V. A., Kirmani, J., Moussavi, M., Doraiswamy, V., Katapally, R., Korya, D., et al. (2012) 'Predictors and outcomes of pneumonia in patients with spontaneous intracerebral hemorrhage.' *J Intensive Care Med*, 28(2), Mar-Apr, 2012, pp. 118-123.

Anderson, C. S., Arima, H., Lavados, P., Billot, L., Hackett, M. L., Olavarría, V. V., Muñoz Venturelli, P., Brunser, A., et al. (2017) 'Cluster-Randomized, Crossover Trial of Head Positioning in Acute Stroke.' *New England Journal of Medicine*, 376(25) pp. 2437-2447.

Aoki, S., Hosomi, N., Hirayama, J., Nakamori, M., Yoshikawa, M., Nezu, T., Kubo, S., Nagano, Y., et al. (2016) 'The Multidisciplinary Swallowing Team Approach Decreases Pneumonia Onset in Acute Stroke Patients.' *PloS one*, 11(5) e0154608-e0154608.

Arai, N., Nakamizo, T., Ihara, H., Koide, T., Nakamura, A., Tabuse, M. and Miyazaki, H. (2017) 'Histamine H2-Blocker and Proton Pump Inhibitor Use and the Risk of Pneumonia in Acute Stroke: A Retrospective Analysis on Susceptible Patients.' *PLoS One*, 12(1) 2017/01/13, p.e0169300.

Arnold, M., Liesirova, K., Broeg-Morvay, A., Meisterernst, J., Schlager, M., Mono, M. L., El-Koussy, M., Kägi, G., et al. (2016) 'Dysphagia in Acute Stroke:

Incidence, Burden and Impact on Clinical Outcome.' *PLoS One*, 11(2) 2016/02/11, p. e0148424.

Baker, S. E. and Edwards, R. (2012) *How Many Qualitative Interviews is Enough? Expert Voices and Early Career Reflections on Sampling and Cases in Qualitative Research.* https://eprints.ncrm.ac.uk/id/eprint/2273/4/how_many_interviews.pdf.

Bax, L., McFarlane, M., Green, E. and Miles, A. (2014) 'Speech-language pathologist-led fiberoptic endoscopic evaluation of swallowing: functional outcomes for patients after stroke.' *J Stroke Cerebrovasc Dis*, 23(3), Mar, 2013/12/24, pp. e195-200.

Beavan, J. (2015) 'Update on management options for dysphagia after acute stroke.' *British Journal of Neuroscience Nursing*, 11(Sup2) pp. 10-19.

Beavan, J., Conroy, S. P., Harwood, R., Gladman, J. R., Leonardi-Bee, J., Sach, T., Bowling, T., Sunman, W., et al. (2010) 'Does looped nasogastric tube feeding improve nutritional delivery for patients with dysphagia after acute stroke? A randomised controlled trial.' *Age Ageing*, 39(5), Sep, 2010/07/27, pp. 624-630.

Benfield, J. and Michou, E. (2016) 'Dysphagia screening and assessment in the stroke unit.' *British Journal of Neuroscience Nursing*, 12(Sup2) pp. S24-S28.

Bevan, J. (2015) 'Update on management options for dysphagia after acute stroke.' *British Journal of Neuroscience Nursing*, 11, 27 April 2015,

Blair, J., Czaja, R. and Blair, E. (2014) Designing Surveys: A Guide to Decisions and Procedures. 3rd Edition ed.: Thousand Oaks, CA:Sage.

Boaden, L. and Davis, S. (2006) Inter Professional Dysphagia Framework. In: Storey, L. and Watkins, C.: National Dysphagia Competence Steering Group

Boaden E, Burnell J, Hives L, Dey P, Clegg A, Lyons MW, Lightbody CE, Hurley MA, Roddam H, McInnes E, Alexandrov A, Watkins CL. Screening for aspiration risk associated with dysphagia in acute stroke. Cochrane Database of Systematic Reviews 2021, Issue 10. Art. No.: CD012679. DOI: 10.1002/14651858.CD012679.pub2.

Booth, A. (2008) 'Unpacking your literature search toolbox: on search styles and tactics.' *Health Info Libr J*, 25(4), Dec, 2008/12/17, pp. 313-317.

Braun, V. and Clarke, V. (2006) 'Using thematic analysis in psychology.' *Qualitative Research in Psychology*, 3(2), 2006/02/01, pp. 77-101.

Bray, B. D., Smith, C. J., Cloud, G. C., Enderby, P., James, M., Paley, L., Tyrrell, P. J., Wolfe, C. D., et al. (2017) 'The association between delays in screening for and assessing dysphagia after acute stroke, and the risk of stroke-associated pneumonia.' *J Neurol Neurosurg Psychiatry*, 88(1), pp. 25-30.

Brogan, E., Langdon, C., Brookes, K., Budgeon, C. and Blacker, D. (2014) 'Dysphagia and factors associated with respiratory infections in the first week post stroke.' *Neuroepidemiology*, 43(2), pp. 140-144.

Brogan, E., Langdon, C., Brookes, K., Budgeon, C. and Blacker, D. (2015) 'Can't swallow, can't transfer, can't toilet: factors predicting infections in the first week post stroke.' *J Clin Neurosci*, 22(1), pp. 92-97.

Bryman, A. (2006) 'Integrating quantitative and qualitative research: how is it done?' *Qualitative Research*, 6(1) pp. 97-113.

Burgess , R. and Moorhead, J. (2011) *New Principles of Best Practice in Clinical Audit.* CRC Press.

Burns, K. E., Duffett, M., Kho, M. E., Meade, M. O., Adhikari, N. K., Sinuff, T. and Cook, D. J. (2008) 'A guide for the design and conduct of self-administered surveys of clinicians.' *Cmaj*, 179(3), Jul 29, pp. 245-252.

Caldeira, D., Alarcão, J., Vaz-Carneiro, A. and Costa, J. (2012) 'Risk of pneumonia associated with use of angiotensin converting enzyme inhibitors and angiotensin receptor blockers: systematic review and meta-analysis.' *BMJ : British Medical Journal*, 345 p. e4260.

Campbell, P., Bain, B., Furlanetto, D. L. C. and Brady, M. C. (2020) 'Interventions for improving oral health in people after stroke.' *Cochrane Database of Systematic Reviews*, (12)

Casaubon, L. K., Boulanger, J. M., Blacquiere, D., Boucher, S., Brown, K., Goddard, T., Gordon, J., Horton, M., et al. (2015) 'Canadian Stroke Best Practice Recommendations: Hyperacute Stroke Care Guidelines, Update 2015.' *Int J Stroke*, 10(6), Aug, 2015/07/07, pp. 924-940.

CASP. (2017) *CASP Checklists*. [Online] [Accessed on 14 October 2017] https://casp-uk.net/casp-tools-checklists/

Centre for Reviews and Dissemination. Systematic Reviews: Guidance for Undertaking Reviews in Healthcare (2009). https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf [Online] [Accessed on October 14, 2017].

Chaves M.L, Gittins M., Bray B., Vail A., Smith C.J. Variation of stroke-associated pneumonia in stroke units across England and Wales: A registry-based cohort study. Int J Stroke. 2022 Feb;17(2):155-162. doi: 10.1177/17474930211006297. Epub 2021 Apr 9. PMID: 33724106; PMCID: PMC8821977.

Cieplik, F., Wiedenhofer, A. M., Pietsch, V., Hiller, K.-A., Hiergeist, A., Wagner, A., Baldaranov, D., Linker, R. A., et al. (2020) 'Oral Health, Oral Microbiota, and Incidence of Stroke-Associated Pneumonia-A Prospective Observational Study.' *Frontiers in neurology*, 11 p. 528056.

Colodny, N. (2002) 'Interjudge and intrajudge reliabilities in fiberoptic endoscopic evaluation of swallowing (fees) using the penetration-aspiration scale: a replication study.' *Dysphagia*, 17(4), Fall, 2002/10/02, pp. 308-315.

Care Quality Commission. Guidance for Providers. 2018. Available online: https://www.cqc.org.uk/guidance-providers/learning-safety-incidents/issue-6-caring-people-risk-choking (accessed on 19 June 2019).

Crary, M., Carnaby Mann, G. and Groher, M. (2005) 'Initial Psychometric Assessment of a Functional Oral Intake Scale for Dysphagia in Stroke Patients.' *Archives of Physical Medicine and Rehabilitation,* 86, pp. 1516-1520. [Online] 8. [Accessed on 6 February 2022] https://doi.org/10.1016/j.apmr.2004.11.049

Creswell, J. W. and Plano Clark, V. L. (2018) *Designing and conducting mixed methods research.* Los Angeles: SAGE.

Daniels, S. K., Anderson, J. A. and Willson, P. C. (2012) 'Valid items for screening dysphagia risk in patients with stroke: a systematic review.' *Stroke 2012 Mar;43(3):892-7 doi: 10 1161/STROKEAHA 111 640946 Epub 2012 Feb 2*, (3) pp. 892-897.

Dhufaigh, N. N. and Hayes, M. (2017) '128The Sooner the Better: Does Early Speech and Language Therapy Involvement in Stroke Management Result in Better Dysphagia Outcomes?' *Age and Ageing*, 46(Suppl_3) pp. iii13-iii59.

DerSimonian, R. and Laird, N. (2015) 'Meta-analysis in clinical trials revisited.' *Contemp Clin Trials*, 45(Pt A), Nov, 2015/09/08, pp. 139-145.

Dhufaigh, N. N. and Hayes, M. (2017) '128The Sooner the Better: Does Early Speech and Language Therapy Involvement in Stroke Management Result in Better Dysphagia Outcomes?' *Age and Ageing*, 46(Suppl_3) pp. iii13-iii59.

Dillman, D. (2008) Total design method (tdm). In: Lavrakas, P. *Encyclopedia of survey research methods*. pp. 893-896. Thousand Oaks, CA: SAGE Publications, Inc.

Dillman, D. A., Smyth, J. D. and Christian, L. M. (2014) *Internet , phone, mail, and mixed mode surveys: The tailored design method.* 4th edition ed., 0475 Crosspoint Boulevard, Indianapolis, IN 46256: John Wiley & Sons Inc.

Dirnagl, U., Klehmet, J., Braun, J. S., Harms, H., Meisel, C., Ziemssen, T., Prass, K. and Meisel, A. (2007) 'Stroke-induced immunodepression: experimental evidence and clinical relevance.' *Stroke*, 38(2 Suppl), Feb, pp. 770-773.

Dziewas, R., Michou, E., Trapl-Grundschober, M., Lal, A., Arsava, E. M., Bath, P. M., Clavé, P., Glahn, J., et al. (2021a) 'European Stroke Organisation and European Society for Swallowing Disorders guideline for the diagnosis and treatment of post-stroke dysphagia.' *European Stroke Journal*, 6(3) pp. LXXXIX-CXV.

Dziewas, R., Warnecke, T., Allescher, H. D., Aroyo, I., Bartolome, G., Beilenhoff, U., Bohlender, J., Breitbach-Snowdon, H., et al. (2021b) 'Diagnosis and treatment of neurogenic dysphagia - S1 guideline of the German Society of Neurology.' 3(1)

Elkind, M. S., Boehme, A. K., Smith, C. J., Meisel, A. and Buckwalter, M. S. (2020) 'Infection as a stroke risk factor and determinant of outcome after stroke.' *Stroke*, 51(10) pp. 3156-3168.

Eltringham, S.A., Bray, B.D, Smith C.J., Pownall S., Sage K. 'Are Differences in Dysphagia Assessment, Oral Care Provision, or Nasogastric Tube Insertion Associated with Stroke-Associated Pneumonia? A Nationwide Survey Linked to National Stroke Registry Data.' Cerebrovasc Dis. 2021 Dec 16:1-8. doi: 10.1159/000519903. Epub ahead of print. PMID: 34915473.

Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Smith, C. J. and Pownall, S. (2020) 'Factors Associated with Risk of Stroke-Associated Pneumonia in Patients with Dysphagia: A Systematic Review.' *Dysphagia*, 35(5), Oct, 2019/09/08, pp. 735-744.

Eltringham, S. A., Smith, C. J., Pownall, S., Sage, K. and Bray, B. (2019a) 'Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study.' *Geriatrics (Basel)*, 4(4), Oct 25, 2019/11/17.

Eltringham, S. A., Pownall, S., Bray, B., Smith, C. J., Piercy, L. and Sage, K. (2019b) 'Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers.' *Geriatrics (Basel)*, 4(4), Dec 7, 2019/12/11.

Eltringham S, Pownall S, Sage K, Piercy L, Bray B and Smith CJ 237 Service user involvement in the analysis of qualitative data UK Stroke forum 2019 Abstract Supplement. (2019c). *International Journal of Stroke*, *14*(4_suppl), 9–55. https://doi.org/10.1177/1747493019882907

Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Pownall, S. and Smith, C. J. (2018) 'Impact of Dysphagia Assessment and Management on Risk of Stroke-Associated Pneumonia: A Systematic Review.' *Cerebrovasc Dis*, 46(3-4) 2018/09/10, pp. 99-107.

Emsley, H. C. A. and Hopkins, S. J. (2008) 'Acute ischaemic stroke and infection: recent and emerging concepts.' *The Lancet Neurology*, 7 pp. 341-353.

Enderby, P. and John, A. (2015) *Therapy outcome measures for rehabilitation professionals.* Third Edition ed., Guildford: J & R Press Ltd.

Esposito, P. and Dal Canton, A. (2014) 'Clinical audit, a valuable tool to improve quality of care: General methodology and applications in nephrology.' *World J Nephrol*, 3(4), Nov 6, pp. 249-255.

European Stroke Organisation (ESO) Executive Committee; ESO Writing Committee: Guidelines for management of ischaemic stroke and transient ischaemic attack. Cerebrovasc Dis 2008;25:457–507.

Everton, L.F., Benfield, J.K., Hedstrom, A. *et al.* Psychometric assessment and validation of the dysphagia severity rating scale in stroke patients. *Sci Rep* 10, 7268 (2020). https://doi.org/10.1038/s41598-020-64208-9

Eysenbach, G. (2004) 'Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES).' *Journal of medical Internet research*, 6(3) pp. e34-e34.

Field, M., Wenke, R., Sabet, A., Lawrie, M. and Cardell, E. (2018) 'Implementing Cough Reflex Testing in a Clinical Pathway for Acute Stroke: A Pragmatic Randomised Controlled Trial.' *Dysphagia*, 33(6), Dec, 2018, pp. 827-839.
Flader, C. M., Rosendahl, C. and Günther, T. (2017) 'Leitlinienkonforme Dysphagiediagnostik.' *Der Nervenarzt*, 88(10), 2017/10/01, pp. 1168-1176

Finlayson, O., Kapral, M., Hall, R., Asllani, E., Selchen, D. and Saposnik, G. (2011) 'Risk factors, inpatient care, and outcomes of pneumonia after ischemic stroke.' *Neurology*, 77(14) pp. 1338-1345.

Fish, J. (2011) 'Rankin Scale.' *In* Kreutzer, J. S., DeLuca, J. and Caplan, B. (eds.) *Encyclopedia of Clinical Neuropsychology*. New York, NY: Springer New York, pp. 2110-2112. [Fish2011] https://doi.org/10.1007/978-0-387-79948-3_1829

Gandolfi, M., Smania, N., Bisoffi, G., Squaquara, T., Zuccher, P. and Mazzucco, S. (2014) 'Improving post-stroke dysphagia outcomes through a standardized and multidisciplinary protocol: an exploratory cohort study.' *Dysphagia*, 29(6), Dec, 20140813, pp. 704-712.

Gordon, J., Franklin, S. and Eltringham, S. A. (2018) 'Service user reflections on the impact of involvement in research.' *Research Involvement and Engagement*, 4(1) p. 11.

Gorelick, P. B. (2019) 'The global burden of stroke: persistent and disabling.' *Lancet Neurol*, 18(5), May, 2019/03/11, pp. 417-418.

Gosney, M., Martin, M. V. and Wright, A. E. (2006) 'The role of selective decontamination of the digestive tract in acute stroke.' *Age Ageing*, 35(1), Jan, pp. 42-47.

Groves, R., Cialdini, R. and Couper, M. (1992) Understading the decision to participate in a survey. *Public Opinion Quarterly*, Volume 56, Issue 4, WINTER 1992, Pages 475–495, https://doi.org/10.1086/269338

Han, T. S., Lean, M. E., Fluck, D., Affley, B., Gulli, G., Patel, T., Barrett, C., Kakar, P., et al. (2018) 'Impact of delay in early swallow screening on pneumonia, length of stay in hospital, disability and mortality in acute stroke patients.' *European Journal of Clinical Nutrition*, 72(11) pp. 1548-1554.

Hannawi, Y., Hannawi, B., Rao, C. P. V., Suarez, J. I. and Bershad, E. M. (2013) 'Stroke-Associated Pneumonia: Major Advances and Obstacles.' *Cerebrovascular Diseases*, 35(5) pp. 430-443.

Hayes, H., Buckland, S. and Tarpey, M. (2012) *Briefing notes for researchers: public involvement in NHS, public health and social care research.* Eastleigh: INVOLVE.

Herbert, R., Gregory, E. and Haw, C. (2019) 'Collaborative design of accessible information with people with aphasia.' *Aphasiology*, 33(12) pp. 1504-1530.

Higgins J.P.T., Green S., editors. Cochrane handbook for systematic reviews of interventions, Version 5.1.0. The Cochrane Collaboration; 2011. www.handbook.cochrane.org. Updated March 2011.

Higgins, J. P. T., Thompson, S. G., Deeks, J. J. and Altman, D. G. (2003) 'Measuring inconsistency in meta-analyses.' *BMJ*, 327(7414) pp. 557-560.

Hinchey, J. A., Shephard, T., Furie, K., Smith, D., Wang, D. and Tonn, S. (2005) 'Formal dysphagia screening protocols prevent pneumonia.' *Stroke*, 36(9), Sep, 2005/08/20, pp. 1972-1976.

Hoffmann, S., Harms, H., Ulm, L., Nabavi, D. G., Mackert, B.-M., Schmehl, I., Jungehulsing, G. J., Montaner, J., et al. (2017) 'Stroke-induced

immunodepression and dysphagia independently predict stroke-associated pneumonia - The PREDICT study.' *Journal of cerebral blood flow and metabolism : official journal of the International Society of Cerebral Blood Flow and Metabolism*, 37(12) pp. 3671-3682.

Hoffmeister, L., Lavados, P. M., Comas, M., Vidal, C., Cabello, R. and Castells, X. (2013) 'Performance measures for in-hospital care of acute ischemic stroke in public hospitals in Chile.' 13(1) p. 23.

Homans, G. C. (1958) 'Social Behavior as Exchange.' *American Journal of Sociology*, 63(6) pp. 597-606.

Horan, T. C., Andrus, M. and Dudeck, M. A. (2008) 'CDC/NHSN surveillance definition of health care-associated infection and criteria for specific types of infections in the acute care setting.' *Am J Infect Control*, 36(5), Jun, 2008/06/10, pp. 309-332.

Huang, J. Y., Zhang, D. Y., Yao, Y., Xia, Q. X. and Fan, Q. Q. (2006) 'Training in swallowing prevents aspiration pneumonia in stroke patients with dysphagia.' *J Int Med Res*, 34(3), May-Jun, pp. 303-306.

Initiative IDDSI. Complete IDDSI framework detailed definitions. 2019. Available from: https://iddsi.org/IDDSI/media/images/Complete_IDDSI_Framework_Final_31July2019.pdf2019.

Ilott, I., Gerrish, K., Eltringham, S. A., Taylor, C. and Pownall, S. (2016) 'Exploring factors that influence the spread and sustainability of a dysphagia innovation: an instrumental case study.' *BMC Health Serv Res*,16 (1) p. 406.

informme.org. (2017) *Clinical Guidelines for Stroke Management*. [Online] [Accessed https://informme.org.au/Guidelines/Clinical%20Guidelines%20for%20Stroke%20Management%202017

Inui, Y., Kamakura, Y., Fukada, J., Yoneda, M., Kataoka, E., Usami, Y., Sugiura, M., Nagatani, T., et al. (2017) 'Development of Pyriform Sinus Suctioning Programs for Aspiration Pneumonia Prevention During the Acute Stroke.' *Dysphagia*, 32(6) pp. 767-776.

ISWP. (2016a) *National clinical guideline for stroke: Evidence tables*. London: Royal College of Physicians. [Online] [Accessed on 18 October 2017] https://www.strokeaudit.org/Guideline/Appendices.aspx

ISWP. (2016b) National Clinical Guideline for Stroke. Fifth edition ed. London: Royal College of Physicians.

Jauch, E. C., Saver, J. L., Adams, H. P., Jr., Bruno, A., Connors, J. J., Demaerschalk, B. M., Khatri, P., McMullan, P. W., Jr., et al. (2013) 'Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association.' *Stroke*, 44(3) pp. 870-947.

JLA. (2021) 'Stroke Prevention, Diagnosis, Pre hospital and Hospital Care Top 10 Priorities.' [Online]. [Accessed on 03/08/2021] https://www.jla.nihr.ac.uk/priority-setting-partnerships/Stroke/stroke-prevention-diagnosis-pre-hospital-and-hospital-care-top-10-priorities.htm

Joundi, R. A., Martino, R., Saposnik, G., Giannakeas, V., Fang, J. and Kapral, M. K. (2017) 'Predictors and Outcomes of Dysphagia Screening After Acute Ischemic Stroke.' (1524-4628 (Electronic))

Julier, R. and Benfield, J. K. (2021) 'Evaluating the Use of Oral Trials for Inpatient Dysphagia Management: An Initial Cross-Sectional Database Study.' *Am J Speech Lang Pathol*, 30(4), Jul 14, 20210623, pp. 1793-1804.

Kalra, L., Hodsoll, J., Irshad, S., Smithard, D. and Manawadu, D. (2016) 'Association between nasogastric tubes, pneumonia, and clinical outcomes in acute stroke patients.' *Neurology*, 87(13) pp. 1352-1359.

Kalra, L., Irshad, S., Hodsoll, J., Simpson, M., Gulliford, M., Smithard, D., Patel, A. and Rebollo-Mesa, I. (2015) 'Prophylactic antibiotics after acute stroke for reducing pneumonia in patients with dysphagia (STROKE-INF): a prospective, cluster-randomised, open-label, masked endpoint, controlled clinical trial.' *The Lancet*, 386(10006), 2015/11/07, pp. 1835-1844.

Katzan, I. L., Cebul, R. D., Husak, S. H., Dawson, N. V. and Baker, D. W. (2003) 'The effect of pneumonia on mortality among patients hospitalized for acute stroke.' *Neurology*, 60(4), Feb 25, pp. 620-625.

Katzan, I. L., Dawson, N. V., Thomas, C. L., Votruba, M. E. and Cebul, R. D. (2007) 'The cost of pneumonia after acute stroke.' *Neurology*, 68(22) pp. 1938-1943.

Keusch, F. (2015) 'Why do people participate in Web surveys? Applying survey participation theory to Internet survey data collection.' *Management Review Quarterly*, 65(3) pp. 183-216.

Kishore, A., Vail, A., Chamorro, A., Garau, J., Hopkins, S., Di Napoli, M., Kalra, L., Langhorne, P., et al. (2015) 'How Is Pneumonia Diagnosed in Clinical Stroke Research?' *Stroke*, 46(5) pp. 1202-1209.

Kishore, A. K., Vail, A., Jeans, A. R., Chamorro, A., Di Napoli, M., Kalra, L., Langhorne, P., Roffe, C., et al. (2018) 'Microbiological Etiologies of Pneumonia Complicating Stroke: A Systematic Review.' *Stroke*, 49(7), Jul, 2018/06/18, pp. 1602-1609.

Kubler-Ross, E. (1969) *On Death and Dying.* The Macmillian Company: New York, NY, USA.

Kvale, S. (2007) *Doing Interviews.* The Sage Qualitative Research Kit. London: SAGE Publications Limited.

Langdon, P. C., Lee, A. H. and Binns, C. W. (2009) 'High Incidence of Respiratory Infections in 'Nil by Mouth' Tube-Fed Acute Ischemic Stroke Patients.' *Neuroepidemiology*, 32(2) pp. 107-113.

Langmore SE, Terpenning MS, Schork A, Chen Y, Murray JT, Lopatin D, Loesche WJ. Predictors of aspiration pneumonia: how important is dysphagia? Dysphagia. 1998 Spring;13(2):69-81. doi: 10.1007/PL00009559. PMID: 9513300.

Lavrakas, P. J. (2008) *Encyclopedia of survey research methods*. (Accessed 22 July 2020) Vol. 0. Thousand Oaks, CA, : Sage Publications, Inc.

Leder, S. B. and Espinosa, J. F. (2002) 'Aspiration risk after acute stroke: comparison of clinical examination and fiberoptic endoscopic evaluation of swallowing.' *Dysphagia*, 17(3), Summer, 2002/07/26, pp. 214-218.

Leder, S. B. and Suiter, D. M. (2014) *The Yale Swallow Protocol: An Evidence-Based Approach to Decision Making.* Springer International Publishing.

Locock, L., Kirkpatrick, S., Brading, L., Sturmey, G., Cornwell, J., Churchill, N. and Robert, G. (2019) 'Involving service users in the qualitative analysis of patient narratives to support healthcare quality improvement.' *Research Involvement and Engagement*, 5(1) p. 1.

Longhurst, L. (2018) 'Prioritising areas for research ' [Online]. [Accessed on 03/08/2021] https://www.rcslt.org/wp-content/uploads/media/Project/Bulletins/bulletin-may-2018.pdf

Lyons, M., Smith, C., Boaden, E., Brady, M. C., Brocklehurst, P., Dickinson, H., Hamdy, S., Higham, S., et al. (2018) 'Oral care after stroke: Where are we now?' *Eur Stroke J*, 3(4), Dec, 2018/05/08, pp. 347-354.

Maeshima, S., Osawa, A., Hayashi, T. and Tanahashi, N. (2014) 'Elderly age, bilateral lesions, and severe neurological deficit are correlated with stroke-associated pneumonia.' *J Stroke Cerebrovasc Dis*, 23(3), Mar, 2013/05/15, pp. 484-489.

Mann, G. (2002) *MASA, the Mann Assessment of Swallowing Ability.* Singular Thomson Learning.

Martino, R., Foley, N., Bhogal, S., Diamant, N., Speechley, M. and Teasell, R. (2005) 'Dysphagia after stroke: incidence, diagnosis, and pulmonary complications.' *Stroke.*, 36(12), Dec, pp. 2756-2763. doi 2710.1161/2701.STR.0000190056.0000176543.eb. Epub 0000192005 Nov 0000190053.

Martino, R., Silver, F., Teasell, R., Bayley, M., Nicholson, G., Streiner, D. L. and Diamant, N. E. (2009) 'The Toronto Bedside Swallowing Screening Test (TOR-BSST): development and validation of a dysphagia screening tool for patients with stroke.' *Stroke*, 40(2), pp. 555-561.

Mason, J. (2009) *Qualitative Researching.* Second edition. ed.: SAGE Publications Ltd.

McAllister, S., Kruger, S., Doeltgen, S. and Tyler-Boltrek, E. (2016) 'Implications of Variability in Clinical Bedside Swallowing Assessment Practices by Speech Language Pathologists.' *Dysphagia*, 31(5) pp. 650-662.

McAllister, S., Tedesco, H., Kruger, S., Ward, E. C., Marsh, C. and Doeltgen, S. H. (2020) 'Clinical reasoning and hypothesis generation in expert clinical swallowing examinations.' *Int J Lang Commun Disord*, 55(4), Jul, 2020/03/19, pp. 480-492.

Merner, B., Hill, S. and Taylor, M. (2019) '"I'm Trying to Stop Things Before They Happen": Carers' Contributions to Patient Safety in Hospitals.' *Qualitative Health Research*, 29(10), 2021/09/28, pp. 1508-1518.

Millar, M. M. and Dillman, D. A. (2011) 'Improving Response to Web and Mixed-Mode Surveys.' *Public Opinion Quarterly*, 75(2) pp. 249-269.

Moher, D., Liberati, A., Tetzlaff, J. and Altman, D. (2009) 'The PRISMA Group (2009) Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement.' *PLoS Med*, 6(7)

Morris, S., Ramsay, A. I. G., Boaden, R. J., Hunter, R. M., McKevitt, C., Paley, L., Perry, C., Rudd, A. G., et al. (2019) 'Impact and sustainability of centralising acute stroke services in English metropolitan areas: retrospective analysis of hospital episode statistics and stroke national audit data.' *Bmj*, 364, Jan 23, 2019/01/23, p. l1.

Nakamori, M., Imamura, E., Tachiyama, K., Kamimura, T., Hayashi, Y., Matsushima, H., Kuwabara, M., Funai, M., et al. (2020) 'Simplified cough test can predict the risk for pneumonia in patients with acute stroke.' PLoS One. 2020; 15(9): e0239590

Neyeloff, J. L., Fuchs, S. C. and Moreira, L. B. (2012) 'Meta-analyses and Forest plots using a microsoft excel spreadsheet: step-by-step guide focusing on descriptive data analysis.' *BMC Res Notes*, 5, Jan 20, 2012/01/24, p. 52.

NHLBI. (2017) *Study Quality Assessment Tools*. Quality Assessment Tool for Before-After (Pre-Post) Studies With No Control Group. [Online] [Accessed on October 18 2017] https://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/before-after

NHS. (2019) *Stroke*. https://www.nhs.uk/conditions/stroke/ [Online] [Accessed on 29 June 2019]

NHS Improvement. (2016) Patient Safety Alert. *Nasogastric tube misplacement: continuing risk of death and severe harm. 22 July 2016. [Accessed on 8 February 2022] https://www.england.nhs.uk/wp-content/uploads/2019/12/Patient_Safety_Alert_Stage_2_-_NG_tube_resource_set.pdf*

NICE (2019) 'Stroke and transient ischaemic attack in over 16s: diagnosis and initial management NICE guideline [NG128] ' [Online]. [Accessed on 24 March 2021]

NIHR Centre for Reviews and Dissemination - CRD Database. https://www.crd.york.ac. uk/CRDWeb/ [Online]. [Accessed on October 14, 2017].

NIHR National Standards for Public Involvement in Research V1 March 2018. Available online: https://sites.google.com/nihr.ac.uk/pi-standards/home (accessed on 9 October 2019).

O'Brien, B. C., Harris, I. B., Beckman, T. J., Reed, D. A. and Cook, D. A. (2014) 'Standards for reporting qualitative research: a synthesis of recommendations.' *Acad Med*, 89(9), Sep, pp. 1245-1251.

Odderson, I. R. and McKenna, B. S. (1993) 'A model for management of patients with stroke during the acute phase. Outcome and economic implications.' *Stroke*, 24(12), Dec, 1993/12/01, pp. 1823-1827.

Odderson, I. R., Keaton, J. C. and McKenna, B. S. (1995) 'Swallow management in patients on an acute stroke pathway: quality is cost effective.' *Arch Phys Med Rehabil*, 76(12), Dec, 1995/12/01, pp. 1130-1133.

Oliva-Moreno, J., Peña-Longobardo, L. M., Mar, J., Masjuan, J., Soulard, S., Gonzalez-Rojas, N., Becerra, V., Casado, M., et al. (2018) 'Determinants of Informal Care, Burden, and Risk of Burnout in Caregivers of Stroke Survivors: The CONOCES Study.' *Stroke*, 49(1), Jan, 2017/11/28, pp. 140-146.

Ouyang, M., Boaden, E., Arima, H., Lavados, P. M., Billot, L., Hackett, M. L., Olavarría, V. V., Muñoz-Venturelli, P., et al. (2020) 'Dysphagia screening and

risks of pneumonia and adverse outcomes after acute stroke: An international multicenter study.' *Int J Stroke*, 15(2), Feb, 2019/06/21, pp. 206-215.

Palli, C., Fandler, S., Doppelhofer, K., Niederkorn, K., Enzinger, C., Vetta, C., Trampusch, E., Schmidt, R., et al. (2017) 'Early Dysphagia Screening by Trained Nurses Reduces Pneumonia Rate in Stroke Patients: A Clinical Intervention Study.' *Stroke*, 48, pp. 2583-2585.

Park JJH, Harari O, Dron L, Lester RT, Thorlund K, Mills EJ. An overview of platform trials with a checklist for clinical readers. J Clin Epidemiol. 2020 Sep;125:1-8. doi: 10.1016/j.jclinepi.2020.04.025. Epub 2020 May 13. PMID: 32416336.

Patient Safety Alert. Resources to Support Safer Modification of Food and Drink. 2018. Available online: https://improvement.nhs.uk/documents/2955/Patient_Safety_Alert_-_Resources_to_support_safer_ modification_of_food_and_drink_v2.pdf (accessed on 19 June 2019).

Patton, M. Q. (2002) *Qualitative Research & Evaluation Methods: Integrating Theory and Practice.* Second edition ed.: Sage Publications Limited.

Perry, L. and McLaren, S. (2000) 'An evaluation of implementation of evidence-based guidelines for dysphagia screening and assessment following acute stroke:phase 2 of an evidence-based practice project.' *Journal of Clinical Excellence*, 2 pp. 147-156.

Pizzorni, N., Valentini, D., Gilardone, M., Scarponi, L., Tresoldi, M., Barozzi, S., Corbo, M. and Schindler, A. (2020) 'The Mealtime Assessment Scale (MAS): Part 2 - Preliminary Psychometric Analysis.' *Folia Phoniatr Logop*, 72(3) 20190417, pp. 182-193.

Porter, S. R., Whitcomb, M. E. and Weitzer, W. H. (2004) *Multiple surveys of students and survey fatigue. New Directions for Institutional Research,* 121*,* 63-73.

Powers, W. J., Rabinstein, A. A., Ackerson, T., Adeoye, O. M., Bambakidis, N. C., Becker, K., Biller, J., Brown, M., et al. (2018) '2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for

Healthcare Professionals From the American Heart Association/American Stroke Association.' *Stroke*, 49(3), Mar, 2018/01/26, pp. e46-e110.

Prass , K., Meisel , C., Höflich , C., Braun , J., Halle , E., Wolf , T., Ruscher , K., Victorov , I. V., et al. (2003) 'Stroke-induced Immunodeficiency Promotes Spontaneous Bacterial Infections and Is Mediated by Sympathetic Activation Reversal by Poststroke T Helper Cell Type 1–like Immunostimulation.' *Journal of Experimental Medicine*, 198(5) pp. 725-736.

Quek, S., Junyang, H. and Ali, A. (2018) 'UK Stroke Forum Abstracts 2018.' *In International Journal of Stroke.* Vol. 13 pp. 10-65. https://journals.sagepub.com/doi/abs/10.1177/1747493018801108

RCSLT (2020) 'RCSLT Webinar: Improving Stroke Care - The impact of Covid-19 present and future.' youtube.com: RCSLT.

Review Manager (RevMan). [Computer program], version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration; 2014.

Redmond, M. V. (2015) Social Exchange Theory. *English Technical Reports and White Papers. 5.*: Iowa State University Digital Repository.

Rosenbek John, C. (1996) 'A penetration-aspiration scale.' *Dysphagia*, 11(2) pp. 93-98.

Schwarz, M., Coccetti, A., Murdoch, A. and Cardell, E. (2018) 'The impact of aspiration pneumonia and nasogastric feeding on clinical outcomes in stroke patients: A retrospective cohort study.' *Journal of Clinical Nursing*, 27(1-2) pp. e235-e241.

Sentinel Stroke National Audit Programme (SSNAP). Clinical Audit April 2013–March 2018 Annual Public Report. National Results. 2019. Available online: https://www.hqip.org.uk/wp-content/uploads/2019/06/apr2017mar2018-ssnap-annualreport-final.pdf (accessed on 21 June 2019).

Sentinel Stroke National Audit Programme (SSNAP). https://wwww.strokeaudit.org [Online]. [Accessed on 5/03/2021]

Serrant-Green, L. (2002) 'Black on black: methodological issues for black researchers working in minority ethnic communities.' *Nurse Res*, 9(4) pp. 30-44.

Sieber, S. D. C. F. p. d. M. (1973) 'The Integration of Fieldwork and Survey Methods.' *American Journal of Sociology*, 78(6) pp. 1335-1359.

Smith, C., J. (2020) 'Can we prevent stroke-associated pneumonia?' *In ESO-WSO Conference*. Virtual conference 7-9 November, 2020.

Smith, C. J. (2021b) 'Infection Preceding Stroke and Complicating Stroke - Epidemiological Evidence.' *In 7th European Stroke Organisation Conference*. Virtual, 1/9/2021.[Accessed on 10/11/2021]

Smith, C. J. (2021a) 'CHlorhexidine Or toothpaSte, manual or powered brushing to prEvent pNeumonia complicating stroke (CHOSEN): a 2x2 factorial randomised controlled feasibility trial.' [Online]. [Accessed on 24/03/2021] https://fundingawards.nihr.ac.uk/award/NIHR200739

Smith, C. J., Kishore, A. K., Vail, A., Chamorro, A., Garau, J., Hopkins, S. J., Napoli, M. D., Kalra, L., et al. (2015) 'Diagnosis of Stroke-Associated Pneumonia: Recommendations From the Pneumonia in Stroke Consensus Group.'*Stroke*, 46(8) pp. 2335-2340.

Smith, E. E., Kent, D. M., Bulsara, K. R., Leung, L. Y., Lichtman, J. H., Reeves, M. J., Towfighi, A., Whiteley, W. N., et al. (2018) 'Effect of Dysphagia Screening Strategies on Clinical Outcomes After Stroke: A Systematic Review for the 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke.' *Stroke*, 49(3), Mar, 2018/01/24, pp. e123-e128.

Smithard, D. G., O'Neill, P. A., Parks, C. and Morris, J. (1996) 'Complications and outcome after acute stroke. Does dysphagia matter?' *Stroke*, 27(7), Jul, 1996/07/01, pp. 1200-1204.

Staniszewska, S., Brett, J., Simera, I., Seers, K., Mockford, C., Goodlad, S., Altman, D. G., Moher, D., et al. (2017) 'GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research.' *BMJ*, 358 p. j3453.

Steele, C. M., Namasivayam-MacDonald, A. M., Guida, B. T., Cichero, J. A., Duivestein, J., Hanson, B., Lam, P. and Riquelme, L. F. (2018) 'Creation and Initial Validation of the International Dysphagia Diet Standardisation Initiative

Functional Diet Scale.' *Arch Phys Med Rehabil*, 99(5), May, 20180208, pp. 934-944

Swan, K., Speyer, R., Heijnen, B. J., Wagg, B. and Cordier, R. (2015) 'Living with oropharyngeal dysphagia: effects of bolus modification on health-related quality of life--a systematic review.' *Qual Life Res*, 24(10), Oct, 2015/04/14, pp. 2447-2456.

Swigert, N. B., Steele, C. and Riquelme , L. F. (2007) 'Dysphagia Screening for Patients with Stroke: Challenges in Implementing a Joint Commission Guideline.' *ASHA Wire.* [Online] Vol. 12. [Accessed on 28/7/2021] https://doi.org/10.1044/leader.FTR1.12032007.4

Trapl, M., Enderle, P., Nowotny, M., Teuschl, Y., Matz, K., Dachenhausen, A. and Brainin, M. (2007) 'Dysphagia bedside screening for acute-stroke patients: the Gugging Swallowing Screen.' *Stroke*, 38(11), pp. 2948-2952.

Teuschl Y, Trapl M, Ratajczak P, Matz K, Dachenhausen A, Brainin M (2018) Systematic dysphagia screening and dietary modifications to reduce stroke-associated pneumonia rates in a stroke-unit. PLoS ONE 13(2): e0192142. https://doi.org/10.1371/journal.pone.0192142

Teuschl, Y., Trapl-Grundschober, M., Ratajczak, P., Matz, K., Dachenhausen, A. and Brainin, M. (2018b) 'Patients with mild as well as with severe acute strokes benefit from systematic dysphagia screening and dietary modification to prevent pneumonia - A registry study.' *In 11th World Stroke Congress*. Montreal, Canada, Researchgate: [Accessed on 17/11/2021] https://www.researchgate.net/publication/329912717_PATIENTS_WITH_MILD_AS_WELL_AS_WITH_SEVERE_ACUTE_STROKES_BENEFIT_FROM_SYSTEMATIC_DYSPHAGIA_SCREENING_AND_DIETARY_MODIFICATION_TO_PREVENT_PNEUMONIA_A_REGISTRY_STUDY/comments

Tuten, T. L. (1997) Getting a foot in the electronic door: understanding why people read or delete electronic mail.: Mannheim: Zentrum für Umfragen, Methoden und Analysen -ZUMA-.

Trimble, J., Patterson , J., Dixit , A., Wilson , J. and Drinnan , M. (2021) *Feasibility of clinical swallowing evaluation and cough reflex testing for silent aspiration in hyper acute stroke.* UK Stroke Forum (Virtual).

'UK Stroke forum 2019 Abstract Supplement.' (2019) *International Journal of Stroke*, 14(4_suppl) pp. 9-55.

van der Worp, H. b. (2017) PRECIOUS: PREvention of Complications to Improve Outcome in elderly patients with acute stroke. A randomised, open, phase III clinical trial with blinded assessment Study Protocol. Version 4 ed.

Vermeij, J. D., Westendorp, W. F., Dippel, D. W., van de Beek, D. and Nederkoorn, P. J. (2018) 'Antibiotic therapy for preventing infections in people with acute stroke.' *Cochrane Database Syst Rev*, 1(1), Jan 22, 2018/01/22, p. Cd008530.

Vermeir, P., Vandijck, D., Degroote, S., Peleman, R., Verhaeghe, R., Mortier, E., Hallaert, G., Van Daele, S., et al. (2015) 'Communication in healthcare: a narrative review of the literature and practical recommendations.' *Int J Clin Pract*, 69(11), Nov, 20150706, pp. 1257-1267.

Wafa, H. A., Wolfe, C. D. A., Emmett, E., Roth, G. A., Johnson, C. O. and Wang, Y. (2020) 'Burden of Stroke in Europe: Thirty-Year Projections of Incidence, Prevalence, Deaths, and Disability-Adjusted Life Years.' *Stroke*, 51(8), Aug, 2020/07/10, pp. 2418-2427.

Warnecke, T., Im, S., Kaiser, C., Hamacher, C., Oelenberg, S. and Dziewas, R. (2017) 'Aspiration and dysphagia screening in acute stroke - the Gugging Swallowing Screen revisited.' *Eur J Neurol*, 24(4), Apr, 2017/03/23, pp. 594-601.

Warnecke, T., Ritter, M. A., Kroger, B., Oelenberg, S., Teismann, I., Heuschmann, P. U., Ringelstein, E. B., Nabavi, D. G., et al. (2009) 'Fiberoptic endoscopic Dysphagia severity scale predicts outcome after acute stroke.' *Cerebrovasc Dis*, 28(3) 2009/07/18, pp. 283-289.

Warusevitane, A., Karunatilake, D., Sim, J., Lally, F. and Roffe, C. (2015) 'Safety and effect of metoclopramide to prevent pneumonia in patients with stroke fed via nasogastric tubes trial.' *Stroke*, 46(2), Feb, 2014/12/16, pp. 454-460.

Westendorp, W. F., Nederkoorn, P. J., Vermeij, J.-D., Dijkgraaf, M. G. and de Beek, D. v. (2011) 'Post-stroke infection: A systematic review and meta-analysis.' *BMC Neurology*, 11(1), 2011/09/20, p. 110.

Wilson, T. C. (10 June 2019) *From professional to patient: Hospital experiences of a stroke survivor*. Nursing Times: [Online] [Accessed on 26 November 2019]

Winek, K., Dames, C., Krasteva-Christ, G., Kummer, W., Meisel, C. and Meisel, A. (2018) 'Post stroke pneumonia.' Meisel, A., 4th European Stroke Organisation Conference, Gothenburg, Sweden, May 2018.

Wästfelt, M., Cao, Y. and Ström, J. O. (2018) 'Predictors of post-stroke fever and infections: a systematic review and meta-analysis.' *BMC Neurol*, 18(1), Apr 23, 20180423, p. 49.

Wilkinson, G., Benfield, J. and Bath, P. (2021) *Swallowing Therapy for Dysphagia in Acute and Sub-Acute Stroke (Cochrane Systematic Review)* Virtual: UK Stroke Forum.

Yuan, D., Wang, X., Wang, Y., Zhang, J. and Chen, S. (2020) 'Intensified Oral Hygiene Care in Stroke-Associated Pneumonia: A Pilot Single-Blind Randomized Controlled Trial.' The Journal of Health Care Organisation, Provision and Financing, Volume 57:1-7

Appendix A – Ethical Approvals

NHS
Health Research Authority

Mrs Sabrina Eltringham
Speech and Language Therapy Department
Royal Hallamshire Hospital, Sheffield Teaching Hospitals
NHS Foundation Trust,
Glossop Road, Sheffield
S10 2JF

Email: hra.approval@nhs.net

31 January 2018

Dear Mrs Eltringham

Letter of HRA Approval

Study title:	**How does variation in assessment and management of dysphagia in acute stroke affect the development of stroke-associated pneumonia?**
IRAS project ID:	**222255**
REC reference:	**18/LO/0096**
Sponsor	**Sheffield Hallam University**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from the HRA website.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found through IRAS.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website.

IRAS project ID	222255

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the HRA website.

Your IRAS project ID is **222255**. Please quote this on all correspondence.

Yours sincerely

Miss Lauren Allen
Assessor

Email: hra.approval@nhs.net

Copy to: *Mr Keith Fildes (Sponsor contact)*
Mr Dipak Patel, Sheffield Teaching Hospitals NHS Foundation Trust (Lead NHS R&D contact)

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [Signed acceptance_TSA PGF 2017]	1	13 April 2017
Covering letter on headed paper [Covering letter]	1	14 December 2017
Covering letter on headed paper [Covering Letter]	2	26 January 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2017-18 TWIMC Letter (PI &D&O)]	1	31 July 2017
Interview schedules or topic guides for participants [Topic guide for staff interviews]	1	14 December 2017
Interview schedules or topic guides for participants [Topic Guide for Patient Interviews]	1	14 December 2017
IRAS Application Form [IRAS_Form_19122017]		19 December 2017
IRAS Checklist XML [Checklist_19122017]		19 December 2017
IRAS Checklist XML [Checklist_22122017]		22 December 2017
Letter from funder [Letter from funder]	1	29 March 2017
Letter from sponsor [Sponsorship Letter]	1	15 December 2017
Letters of invitation to participant [Staff Participant Invitation Letter]	1	14 December 2017
Letters of invitation to participant [Patient-Carer Participant Invitation Letter]	2	26 January 2018
Other [HRA Schedule of Events STH site]	1.1	20 December 2017
Other [HRA Schedule of Events non STH sites]	1.1	20 December 2017
Other [Statement of Activities STH]	1.1	20 December 2017
Other [Statement of Activities non STH]	1.1	20 December 2017
Other [2017-18 TWIMC Letter (EL &PL)]	1	31 July 2017
Other [2017-18 EL Certificate]	1	31 July 2017
Participant consent form [Carer Consent Form]	1	21 January 2018
Participant consent form [Patient Consent Form]	2	26 January 2018
Participant consent form [Staff Participant Consent Form]	1	21 May 2017
Participant information sheet (PIS) [Carer Participation Information Sheet]	1	21 January 2018
Participant information sheet (PIS) [Staff Participant Information Sheet]	1	21 May 2017
Participant information sheet (PIS) [Patient Participant Information Sheet]	2	26 January 2018
Research protocol or project proposal [Project Proposal]	2	26 January 2018
Research protocol or project proposal [TSA_PGF_2016 1_11_16]	2	26 January 2018
Summary CV for Chief Investigator (CI) [Summary CV for CI]	1	14 December 2017
Summary CV for student [Summary CV for student]	1	14 December 2017
Summary CV for supervisor (student research) [Sue Pownall CV]	1	14 December 2017
Summary CV for supervisor (student research) [Craig Smith CV]	1	14 December 2017
Summary CV for supervisor (student research) [Karen Kilner CV]	1	14 December 2017
Summary CV for supervisor (student research) [Ben Bray CV]	1	14 December 2017
Summary CV for supervisor (student research) [Karen Sage CV]	1	14 December 2017

IRAS project ID	222255

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Mr Keith Fildes
Tel: 01142254530
Email: researchsupport@shu.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards?	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	The CI/student is part of care team and has routine access to records of patients admitted to the Neurological Assessment Unit but not the patients admitted to the Hyper Acute Stroke Unit, therefore the applicant has confirmed that only participants admitted to the Neurological Assessment Unit will be included in the research.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and	Yes	**Sheffield site:-** The Statement of Activities and Schedule of Events will

Section	HRA Assessment Criteria	Compliant with Standards?	Comments
	documented		act as the agreement with the site. **All other sites:-** The Statement of Activities and Schedule of Events will act as the agreement with the sites.
4.2	Insurance/indemnity arrangements assessed	Yes	The applicant has confirmed that IRAS A76-2 has been answered incorrectly and the University's insurance/indemnity will cover the design of the research. Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	**Sheffield site:-** No funding will be provided to the site. **All other sites:-** No funding will be provided to the sites.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	Arrangements for securely storing data have been confirmed. Only the student researcher/CI will have access to medical records of participants.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter	Not Applicable	No comments

Sheffield Hallam University

SABRINA ELTRINGHAM <b6039189@my.shu.ac.uk>

Converis - Ethics Review - Approval

converis@shu.ac.uk <converis@shu.ac.uk> 24 January 2018 at 15:06
To: "Eltringham, Sabrina" <Sabrina.A.Eltringham@student.shu.ac.uk>

Dear Sabrina

Title of Ethics Review:How does variation in assessment and management of dysphagia in acute stroke affect the development of stroke-associated pneumonia?

Ethic Review ID: ER5599201

The University has reviewed your ethics application named above and can confirm that the project has been approved.

You are expected to deliver the project in accordance with the University's research ethics and integrity policies and procedures: https://www.shu.ac.uk/research/ethics-integrity-and-practice.

As the Principal Investigator you are responsible for monitoring the project on an ongoing basis and ensuring that the approved documentation is used. The project may be audited by the University during or after its lifetime.

Should any changes to the delivery of the project be required, you are required to submit an amendment for review.

Wishing you success you with your study

IRAS PROJECT ID 222255, REC Reference 18/LO/0096 Confirmation of favourable opinion for substantial amendment

bromley.rec@hra.nhs.uk <noreply@harp.org.uk>

Thu 02/04/2020 11:38

To: ELTRINGHAM, Sabrina (SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST) <sabrina.eltringham@nhs.net>; researchsupport@shu.ac.uk <researchsupport@shu.ac.uk>;

Cc: CARD, Aimee (SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST) <aimee.card@nhs.net>; K.Sage@shu.ac.uk <K.Sage@shu.ac.uk>; POWNALL, Sue (SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST) <sue.pownall2@nhs.net>;

1 attachment

18 LO 0096 IRAS 222255 SA1 Fav Opinion 02 04 20.pdf;

Dear Mrs Eltringham

IRAS project ID:	222255
REC reference:	18/LO/0096
Short Study title:	How does dysphagia assessment in acute stroke affect pneumonia?
Date complete amendment submission received:	24 January 2020
Amendment No./ Sponsor Ref:	Substantial Amendment 1
Amendment Date:	24 January 2020
Amendment Type:	**Substantial**
Outcome of HRA Assessment	**This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.**

I am pleased to confirm that this amendment has been reviewed by the Research Ethics Committee and has received a Favourable Opinion. Please find attached a copy of the Favourable Opinion letter.

HRA and HCRW Approval Status

As detailed above, **this email also constitutes HRA and HCRW Approval for the amendment**. No separate notice of HRA and HCRW Approval will be issued. You should implement this amendment at NHS organisations in England and/or Wales, in line with the conditions outlined in your categorisation email.

- If this study has HRA and HCRW Approval, this amendment may be implemented at participating NHS organisations in England and/or Wales once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England and/or Wales that have NHS Permission, once the conditions detailed in the categorisation section above have been met. For participating NHS organisations in England and/or Wales that do not have NHS Permission, these sites should be covered by HRA and HCRW Approval before the amendment is implemented at them, please see below;
- If this study is awaiting HRA and HCRW Approval, I have passed your amendment to my colleague and you should receive separate notification that the study has received HRA and HCRW Approval, incorporating approval for this amendment.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

If you require further information, please contact [amendments@hra.nhs.uk]amendments@hra.nhs.uk

18/LO/0096/AM01 Please quote this number on all correspondence

Kind regards

Nina Bakhshayesh
Health Research Authority
Level 3, Block B | Whitefriars | Bristol Research Ethics Committee Centre | BS1 2NT
T. 0207 104 8063
E. bromley.rec@hra.nhs.uk
W. www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest.

IRAS Project ID 222255. HRA and HCRW Approval for the Amendment

bromley.rec@hra.nhs.uk <noreply@harp.org.uk>

Thu 27/08/2020 12:24

To:ELTRINGHAM, Sabrina (SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST) <sabrina.eltringham@nhs.net>; researchsupport@shu.ac.uk <researchsupport@shu.ac.uk>;

Cc:r.heron@mmu.ac.uk <r.heron@mmu.ac.uk>;

Dear Mrs Eltringham,

IRAS Project ID:	222255
Short Study Title:	How does dysphagia assessment in acute stroke affect pneumonia?
Amendment No./Sponsor Ref:	NSA 30th July
Amendment Date:	7th July 2020
Amendment Type:	Non Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the guidance in the amendment tool.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

Please contact [amendments@hra.nhs.uk]amendments@hra.nhs.uk for any queries relating to the assessment of this amendment.

Kind regards

Nina Bakhshayesh

Health Research Authority

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

E.amendments@hra.nhs.uk

W. www.hra.nhs.uk

02/09/2020

Project Title: How does variation in assessment and management of dysphagia in acute stroke affect the development of stroke associated pneumonia (SAP)?

EthOS Reference Number: 25470

Certification

Dear Sabrina Eltringham,

The above application was reviewed by the Research Ethics and Governance Team and on the 02/09/2020, was certified. The certification is in place until the end of the project and is based on the documentation submitted with your application.

Application Documents

Document Type	File Name	Date	Version
Additional Documentation	2019 EL PL Cover	27/11/2019	1
Additional Documentation	Information sheet for survey - V3 14_7_20	14/07/2020	3
Additional Documentation	First contact - V3 14_7_20	14/07/2020	3
Additional Documentation	IRAS project ID 222255_Amendment dated 30 July_Locked	30/07/2020	1
Additional Documentation	IRAS Project ID 222255. HRA and HCRW Approval for the Amendment	27/08/2020	1

Conditions of certification

The Research Ethics and Governance Team would like to highlight the following conditions

Adherence to Manchester Metropolitan University's Policies and procedures

This certification is conditional on adherence to Manchester Metropolitan University's Policies, Procedures, guidance and Standard Operating procedures. These can be found on the Manchester Metropolitan University Research Ethics and Governance webpages.

Amendments

If you wish to make a change to this approved application, you will be required to submit an amendment in accordance with Manchester Metropolitan University guidelines. Please contact the Research Ethics and Governance team for advice around how to do this.

We wish you every success with your project.

Research Ethics and Governance Team

Appendix B - Author Contributions

Paper 1

Impact of dysphagia assessment and management on risk of stroke-associated pneumonia: A systematic review

Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Pownall, S. and Smith, C. J. (2018) 'Impact of Dysphagia Assessment and Management on Risk of Stroke-Associated Pneumonia: A Systematic Review.' Cerebrovasc Dis, 46(3-4) 2018/09/11, pp. 99-107.

S.A.E., K.K., K.S, B.D.B, S.P and C.J.S. conceived the study. S.A.E, M.G., K.S. and S.P. were involved in the protocol development, and S.A.E, K.S. and S.P in data analysis. S.A.E. wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Paper 2

Factors associated with risk of stroke-associated pneumonia in patients with dysphagia: A Systematic Review

Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Smith, C. J. and Pownall, S. (2020) 'Factors Associated with Risk of Stroke-Associated Pneumonia in Patients with Dysphagia: A Systematic Review.' Dysphagia, 35(5), Oct, 2019/09/08, pp. 735-744.

S.A.E., K.K., K.S, B.D.B, C.J.S. and S.P. conceived the study. S.A.E, M.G., K.S. and S.P. were involved in the protocol development, and S.A.E, K.S. and S.P in data analysis. S.A.E. wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Paper 3

Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study

Eltringham, S. A., Smith, C. J., Pownall, S., Sage, K. and Bray, B. (2019a) 'Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study.' Geriatrics (Basel), 4(4), Oct 25, 2019/11/17

Conceptualization, S.A.E., C.J.S., S.P., K.S. and B.B.; methodology, S.A.E., C.J.S., S.P., K.S. and B.B.; validation, C.J.S., S.P., K.S. and B.B.; formal analysis, S.A.E.; investigation, S.E; resources, S.A.E. and K.S.; data curation, S.A.E. and K.S.; writing—original draft preparation, S.A.E.; writing—review and editing, S.A.E., C.J.S., S.P., K.S. and B.B.; visualization, S.A.E.; supervision,

C.J.S., S.P., K.S. and B.B. project administration, S.A.E. and K.S; funding acquisition, S.A.E. and K.S.

Paper 4

Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers

Eltringham, S. A., Pownall, S., Bray, B., Smith, C. J., Piercy, L. and Sage, K. (2019b) 'Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers.' Geriatrics (Basel), 4(4), Dec 7, 2019/12/11

Conceptualisation, S.A.E., S.P., B.B., C.J.S. and K.S.; Data curation, S.A.E. and K.S.; Formal analysis, S.A.E.; Funding acquisition, S.A.E. and K.S.; Investigation, S.A.E.; Methodology, S.A.E., S.P., B.B., C.J.S. and K.S.; Project administration, S.A.E. and K.S.; Resources, S.A.E. and K.S.; Supervision, S.P., B.B., C.J.S. and K.S.; Validation, S.P., B.B., C.J.S. and K.S.; Visualization, S.A.E.; Writing—original draft, S.A.E.; Writing—review & editing, S.A.E., S.P., B.B., C.J.S., L.P. and K.S.

Paper 5

Are Differences in Dysphagia Assessment, Oral Care Provision, or Nasogastric Tube Insertion Associated with Stroke-Associated Pneumonia?

Eltringham, S. A., Bray, B. D., Smith, C. J., Pownall, S. and Sage, K. (2021) 'Are Differences in Dysphagia Assessment, Oral Care Provision, or Nasogastric Tube Insertion Associated with Stroke-Associated Pneumonia? A Nationwide Survey Linked to National Stroke Registry Data.'

S.A.E. researched the literature, and S.A.E., B.D.B., C.J.S., S.P., and K.S. conceived the study. S.A.E., B.D.B., C.J.S., S.P., and K.S. were involved in protocol development, S.A.E. and K.S. in gaining ethical approval, S.A.E. in recruitment, and S.A.E. and B.D.B. in data analysis. S.A.E. wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Appendix C – Supplementary Material for the Systematic Reviews

Paper 1

Impact of dysphagia assessment and management on risk of stroke-associated pneumonia: A systematic review

Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Pownall, S. and Smith, C. J. (2018) 'Impact of Dysphagia Assessment and Management on Risk of Stroke-Associated Pneumonia: A Systematic Review.' *Cerebrovasc Dis*, 46(3-4) 2018/09/11, pp. 99-107.

Itemised list of figures and tables:

Available online
https://karger.figshare.com/articles/dataset/Supplementary_Material_for_Impact_of_Dysphagia_Assessment_and_Management_on_Risk_of_Stroke-Associated_Pneumonia_A_Systematic_Review/7067198

Paper 2

Factors associated with risk of stroke-associated pneumonia in patients with dysphagia: A Systematic Review

Eltringham, S. A., Kilner, K., Gee, M., Sage, K., Bray, B. D., Smith, C. J. and Pownall, S. (2020) 'Factors Associated with Risk of Stroke-Associated Pneumonia in Patients with Dysphagia: A Systematic Review.' Dysphagia, 35(5), Oct, 2019/09/08, pp. 735-744.

Itemised list of figures and tables:

Available online https://static-content.springer.com/esm/art%3A10.1007%2Fs00455-019-10061-6/MediaObjects/455_2019_10061_MOESM1_ESM.docx

Appendix D – Supplementary Material for the two interview studies

Paper 3

Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study

Eltringham, S. A., Smith, C. J., Pownall, S., Sage, K. and Bray, B. (2019a) 'Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study.' *Geriatrics (Basel)*, 4(4), Oct 25, 2019/11/17

Itemised list of figures and tables:

Table S1: Summary of Royal College of Physicians Clinical Guideline for Stroke (2016) specifically related to dysphagia screening, assessment and oral care.

Table S2: Topic Guide for Staff Interviews

Table S3: Participant Characteristics

Table S4: Type of Dysphagia Screening Protocol

Table S5: Standards for Reporting Qualitative Research (SRQR)

Available online https://www.mdpi.com/2308-3417/4/4/60

Paper 4

Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers

Eltringham, S. A., Pownall, S., Bray, B., Smith, C. J., Piercy, L. and Sage, K. (2019b) 'Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers.' Geriatrics (Basel), 4(4), Dec 7, 2019/12/11

Itemised list of figures and tables:

Available online https://www.mdpi.com/2308-3417/4/4/67

Appendix E Summary of pilot survey respondent feedback

1. Did you find any questions hard to read?	Respondent feedback	Researcher reflection	Amended wording/question format
Q 9 Does the dysphagia screening protocol only involve water?	*"Is there a better way to say this? Use of the word involving in this sentence makes me think that other things are also involved but I think you want to ask if the swallow screen is 100% a water sip test? If people are doing it in a rush (which I guess some will) this wording might catch them off guard."*	The research team discussed going back to the pilot respondent with three differently worded questions and asking the respondent's opinion about their preferred choice of statement. In the absence of a response from the respondent the question was rephrased.	Does the dysphagia screening protocol only use water (Level 0 Thin Fluids) i.e. 100% water?
Q12 Which IDDSI level consistency do you screen with first?	*"Why is this question/answer formatted differently to the other questions? To me it is no problem but the other people I work have very few IT skills and they are very easily confused by changes like this and I think people might not realise how to select the answer here or again it will confuse them."*	The answer format for this question was a select box where respondents were asked to select one International Dysphagia Diet Standardisation Initiative (IDDSI) level consistency. The researcher reviewed the different types of Qualtrics answer formats and found that the answer format could be changed. Administering questions consistently uses the same principle of ensuring good measurement with interview questions, that is the answer format will be consistent to minimise potential confusion (Fowler, 1995).	Answer format was changed to a single choice answer to be consistent with the other questions.

2. Did you have problems understanding any of the questions?	Respondent feedback	Researcher reflection	Amended wording/question format
Q 14 How applicable are the following reasons for delays in stroke patients being screened for dysphagia in your stroke unit?	*"I think you are asking - what are the main reasons for delays in the swallow screening? I appreciate this is probably not easy to word, as you have identified possible reasons for the delays and are asking people to rate the relevance of the reasons you have selected. Wonder if you could break this up into 2 sentences. e.g. below is a list of factors associated with delays in swallow screening. How relevant are each of these factors for delays in swallow screens in your service… (I am not a qual researcher as you well know and I am sure [name] will tell you of my grammar challenges, but thinking of the people in my team they really need things spelling out in the most basic ways to help them understand)*."	The research team discussed breaking down the question into two sentences as suggested by the respondent. The proposed amendment includes a definition in the first sentence, which is part of the question, to make the question easier to understand. This is one solution to poorly defined terms.	Below is a list of reasons for **delays** in stroke patients being screened for dysphagia. How applicable are each of these reasons for delays in stroke patients being screened for dysphagia in your stroke unit?
Q 22 What International Dysphagia Diet Standardisation Initiative (IDDSI) levels are included in the clinical (bedside) swallow assessment?	*"I am not sure what you are asking here, do you want to know if people have specific cut offs re. their assessment protocols? I would assume the answer to this would be that they trial all relevant consistencies. If so, do you want the responder to click all the options? Perhaps an additional option – all relevant consistencies? If so. Or perhaps you are trying to work out if people don't trial level 6 for e.g. as their hospital does not have access to it."*	The research team reviewed the question objective which was to find out what the typical initial SLT swallow assessment looks like. It was agreed that the question should be refined to make this more explicit. It was acknowledged that there was variation and tailoring of assessments to individual patients but that we want to try find out what a first bedside assessment would typically include. The researcher reflected on her clinical experience that	What International Dysphagia Diet Standardisation Initiative (IDDSI) levels are **typically** included in the first clinical (bedside) swallow assessment?

2. Did you have problems understanding any of the questions?	Respondent feedback	Researcher reflection	Amended wording/question format
	"I answered all that might be considered because it depends on how the patient presents. I guess this is what you were asking but it might be clearer if you ask what 'may be included."	although she may have access to all IDSSI levels, she would not necessarily assess every IDSSI level due to how the patient presents with the previous level assessed with, patient fatigue, engagement and participation.	

3. Were there any questions that you had difficulty providing an answer for?	Respondent feedback	Researcher reflection	Amended wording/question format
Q 10 What is the maximum amount of water given? Please indicate the maximum amount in millilitres (mls). For example, a single teaspoon is approximately 5 mls, therefore if the maximum amount given is 5 teaspoons select 25mls.	*"Swallow screen - this asks for total volume of water given. Ours starts with up to x3 5ml, then up to 6 sips then minimum of 50ml from a beaker (in stepwise progression). This doesn't tally with the given volumes I don't think, and I'm not sure of "sip" volume."*	The researcher discussed within the research team whether there was a need to provide an extra definition about sip size appreciating size of sips vary by men and women and different conditions (experimental vs. natural). As the research team had already agreed it would be helpful to have an 'any other comments' box at the end of the survey to capture these and other kinds of variations that the existing questions don't allow for, the decision was made to not amend the question.	What is the maximum amount of water given? Please indicate the maximum amount in millilitres (mls). For example, a single teaspoon is approximately 5 mls, therefore if the maximum amount given is 5 teaspoons select 25 mls.
"Other"- This refers to the "Other" statement in the questions which ask respondents to evaluate reasons for delays in stroke patients receiving a clinical	*Most respondents identified that they had to put text in the 'Other box and select a rating scale in order to proceed. Some said this made the question difficult to answer if you did not have a "other" reason for delay.*	The researcher reflected on the potential options which were to remove the 'Other' option completely, remove the forced response on the 'Other' free text box to reduce potential respondent frustration or remove the forced response from the whole question. The	Creation of a 'Custom Validation' which required all respondents to respond to all statements except 'Other' but if the respondent was to click on 'Other' they were required still

3. Were there any questions that you had difficulty providing an answer for?	Respondent feedback	Researcher reflection	Amended wording/question format
bedside assessment (and dysphagia screen).	*"This question (Q25) has 2 'Other' boxes and I had to give 2 answers before moving on - is there a way to make the 'Other' boxes optional?"* *"Had to select one of the options before it would let me proceed. Would it be possible to have the "other" boxes as free text, not also requiring an option to be selected?"* *"The ones I found tricky were those regarding causes for delay to assessment (boxes with Likert scales) - these all demanded text within the "other" box, plus selection of a Likert scale rating for the "other" on order to progress to the next page"* *"It wouldn't let me carry on without putting in an answer in "other" and "As with the other page, this page won't let me get past it without putting something in the "other boxes", so I just put the same thing in."* *"the bit with the 'other' where you had to populate in order to proceed. Not really a problem but perhaps worth a comment to instruct people to say 'n/a' if 'other' wasn't relevant. I know it is obvious but since joining my current team I have learned the hard way never to assume people have*	researcher was concerned that removing the 'Other' option completely may introduce bias by assuming the reasons given for the delay in dysphagia screening and specialist swallowing assessment were the only reasons, removing the forced response on the free text option was only partially solving the problem and removing the forced response from the whole question could result in respondents fast forwarding a key question and reducing the amount of data collected. The respondent's suggestion for improvement was to "Give the statements you already have with the evaluations and then separately ask 'are there any other factors that delay screening?' with space for a statement and then an evaluation." Based on this feedback received the 'Other' statement was more clearly defined.	required to engage with the free text box. If there are OTHER reasons that delay screening, please state what they are There was a text box for the respondent to describe and provide an evaluation about how applicable the other reason is. For consistency the 'Other' statements in Q25 were amended.

3. Were there any questions that you had difficulty providing an answer for?	Respondent feedback	Researcher reflection	Amended wording/question format
	any ability to follow instructions or use initiative. Harsh, but true!" *One respondent was unsure about what the appropriate answer was for Other in Q14:* *"when I saw 'Other' I think I thought was part of one of the other statements and I was being asked to give more details" .."until I realised that it was a chance for me to give a statement/reason not already listed" "So I think I answered this part ok [question about delays in SLT ax] - but the earlier question [delays in screening] I think I didn't appreciate it was giving me the option for a whole new statement."*		
Q 8. Are the following involved in the dysphagia screening protocol? (If your stroke unit does not have a written protocol, please indicate if any of the following are involved when screening patients for dysphagia).	*"I am used to 'oromotor test' rather than 'Lingual Motor test' but I guess you meant the same"*	The use of the phrase 'lingual motor test' is based on the wording in the RCP guidance which is based on the terminology used in the literature. The research team agreed that lingual motor test is not a commonly used term in the UK and that most speech and language therapists would use the phrase oro-motor test, even though this may include more than a test of tongue motor function.	Amended to Oro-motor test
Q 21 In your Stroke Unit, what does the clinical (bedside) swallow assessment typically	*"I was slightly hesitant in answering as there is variability (not all SLTs do the same thing and not all patients are the*	The research team agreed that the question should be amended to make	In your Stroke Unit, what does the first clinical (bedside) swallow assessment typically

3. Were there any questions that you had difficulty providing an answer for?	Respondent feedback	Researcher reflection	Amended wording/question format
involve? Please tick all that apply.	*same) so I put what was common to most assessments. Also initial bedside assessment may be different to the follow up assessments and I wasn't sure whether you wanted the first assessment or any assessment so I answered for the first assessment. Perhaps you can make it explicit that it is the first assessment you are asking about and whether its what is most commonly used or all the things that might be included."*	it clear that it was the first clinical bedside assessment.	involve? Please tick all that apply.
Q 32 In patients who are unable to maintain adequate nutrition and fluids orally, please indicate typically the number of hours until an NGT is inserted.	*"This was difficult to answer without an audit - it was a guess - it depends on time of admission, medical cover. My estimate is from when it was determined they were unable to maintain adequate nutrition rather than admission (that might be due to levels of drowsiness or outcome of screen/bedside assessment). Maybe you need to make it clearer what information you want.* *"People on my team would probably struggle to understand this. I think you are asking of the duration between decision to non-oral feed and insertion of NGT?"*	The wording of the question had been abbreviated to its current form following discussion with the research team. However, it was clear from the feedback that respondents were finding it difficult to understand the meaning of the question. The wording in the RCP guidance was reviewed ("Patients with stroke who are unable to maintain adequate nutrition and fluids orally should be considered for nasogastric tube feeding within 24 hours of admission".) The research team revisited the question objective which was about the delay in feeding by the NGT in NBM patients. The point in time was from when the patient was judged not safe	In patients who are unable to maintain adequate nutrition and fluids orally, please indicate typically the number of hours from when the decision is taken to non orally feed and the beginning of feeding by an NGT?

3. Were there any questions that you had difficulty providing an answer for?	Respondent feedback	Researcher reflection	Amended wording/question format
		to swallow and the beginning of feeding by the NGT. The wording of the question was revisited again with the wider supervisory team.	

4. Were there any questions which made you uncertain about what the appropriate answer was?	Respondent feedback	Researcher reflection	Amended wording/question format
Q5 Is the dysphagia screen a screen that was developed by your hospital, or a published dysphagia screen?	*"Our hospital screen is a mix of the two. We had our own hospital one, then adapted it to use the Yale, but we still retained the tsps. So I'm not sure if a third option of a mix of the two is helpful or not, but it's up to you. The 'i' button didn't work so well."*	The researcher's perspective is that if a hospital screen had been adapted from a published screen then this is no longer a published screen so the correct response is "hospital screen" which is what this respondent ticked. It was not felt appropriate to have a third option as most hospital screens are probably based on/adapted from a published screen and adapted. The researcher checked the ℹ️ button and it is working but acknowledged people's computers may behave differently.	Is the dysphagia screen a screen that was developed by your hospital, or a published dysphagia screen? ℹ️
Q9 Does the dysphagia screening protocol only involve water?	*"It depends what you mean by this. When [name] was doing her paper on Nurse swallow assessments, she found that most*	The question had already been amended to make it more explicit that it refers to screens that are 100% water.	Does the dysphagia screening protocol only use water (Level 0 Thin Fluids) i.e. 100% water?

4. **Were there any questions which made you uncertain about what the appropriate answer was?**	Respondent feedback	Researcher reflection	Amended wording/question format
	water swallow screens only tested patients with water (and then based on that, recommendations for diet were made, like the Yale). Our screen only uses water (part 1), not thickened fluids. However, if the patient PASSES the water, they are then observed with level 7 easy to chew (part 2) and if they pass that, depending on dentition, time, fatigue, they are then assessed on level 7 regular (part 3) which may or may not be straight away, or may be the next day. Hence although we only use water as a screen and not thickened fluids, we make sure that our patients are also observed on a diet. It will be really interesting, to see in units that only use water to screen, whether those patient are also observed with a diet. However, this question could also apply to screens that use thickened fluids aswell."	The systematic review (Eltringham er al., 2018) identified that water only screens were used. Some of the other pilot respondents also identified that this is the case in their hospital stroke units, so it felt appropriate to keep this question. Also, the respondents stepwise screen process is not dissimilar to researcher's hospital dysphagia screening protocol where if the patient passes on water, they are only then assessed with diet textures. The respondent indicated this in her response to Q11. Which International Dysphagia Diet Standardisation Initiative (IDDSI) levels are included in the dysphagia screening protocol? It was felt this information would be captured. Additionally, there was Q51 The following question gives you the opportunity to tell us about any other variations in dysphagia screening, assessment and management during the first 7 days of a patient's admission to your stroke unit., to capture these types of variations.	

4. Were there any questions which made you uncertain about what the appropriate answer was?	Respondent feedback	Researcher reflection	Amended wording/question format
Q23 Please describe what postural techniques are assessed? And Q24 Please describe what swallowing manouevres are assessed?	*"Is it worth defining what you mean by swallow manouevres, as I included e.g. multiple swallows, as wasn't sure exactly what info you wanted."*	Based on this feedback a hover button was inserted on both questions and definitions for postural techniques and swallowing manouevres were added. The examples given were based on the ASHA website.	Postural techniques redirect the movement of the bolus in the oral cavity and pharynx and modify pharyngeal dimensions in a systematic way. Examples of postural techniques include chin-down posture, chin-up posture, head rotation (turn to side) and head tilt. These examples are not exhaustive. Manoeuvres are specific strategies that clinicians use to change the timing or strength of particular movements of swallowing. Examples of swallowing manoeuvres include effortful swallow, Mendelsohn manoeuvre, supraglottic swallow and super-supraglottic swallow. These examples are not exhaustive.
Q36 In case of inadvertent NGT removal, what is the maximum number of times reinsertion of the NGT is attempted in any patient?	*"I had to check with the nursing staff re some of the NG related questions (overnight insertion, number of times this is attempted etc). It was fine for me to ask the nursing staff this but there was no option for 'unsure' – though perhaps you*	The researcher reverted to the origin of the question which was the staff interviews (Eltringham et al., 2019a). The responses to the question varied from generally a maximum of three attempts to a more holistic approach	In case of inadvertent NGT removal, what is the maximum number of times reinsertion of the NGT is attempted in any patient?

4. Were there any questions which made you uncertain about what the appropriate answer was?	Respondent feedback	Researcher reflection	Amended wording/question format
AND Q37 Are NGTs inserted over night?	*will gain more information if people do have to search out the answers. NGs are inserted overnight depending on staff working."* *"With some of the NG Tube questions, it may be that there could be a box stating UNSURE, although if you have this option people maybe less inclined to find out the answer. For example, I think we have NGs inserted overnight I'm not sure."* *See also "Don't know".* *"Yes, those regarding NGT placement protocols". This respondent had not been in clinical practice for 5 years.* *"Number of NGT insertions - I think this is still a problem. I suspect clinicians will (unless there really is a maximum number of time for ALL patients) find it difficult to give a maximum number of times based on the setting of individual patients…."Any thoughts - do we really need this or could it be re-phrased e.g. "would >3 NGT attempts be undertaken for some patients based on individualised assessment", or something?"*	from the doctors interviewed. The researcher agreed it is difficult because is there really a maximum number of times for ALL patients? It was agreed by the research team to leave the question in "if informed by the interviews" and giving people the option to populate the free text box and/or adding the additional question to enable respondents to provide further information. There was an acknowledgment that there may be a potential issue with extracting the data and making sense of the free text responses.	

4. Were there any questions which made you uncertain about what the appropriate answer was?	Respondent feedback	Researcher reflection	Amended wording/question format
	"The freetext box is for numbers only (I was able to insert 124!), rather than any other explanatory text, which I appreciate will be difficult to extract/categorise, but may frustrate clinicians."	The response option was set up as free text box so unsure how the respondent was presented with a dropdown number list. Other pilot respondents were able provide free text responses.	The researcher checked the response option.
Q44. How often each day is mouthcare provided to people with dysphagia on the stroke unit?	*"I think it depends on how severe the bad oral hygiene is. Should this question state, typically, how often ….."*	The word typically was inserted into the question.	How often each day is mouth care typically provided to people with dysphagia on the stroke unit? (Now Q45)
"Don't know" –this refers to a respondent being allowed to indicate they do not know the answer to a question, or they do not have an opinion on a particular issue.	*"I felt it might be helpful to be able to select "Don't know" in some questions - but maybe you have made a conscious decision not to offer this as an option, in order to get more detailed and measurable data"* *"I didn't know the answer to this so maybe could do with a 'don't know' option"* *These comments were from respondents who either worked in stroke rehab or who have not been in clinical practice for 5 years.*	The researcher consciously decided not to include a "Don't Know" response or "Neutral" option in the survey due to risk of satisficing, although it was acknowledged some people may genuinely "Don't Know". The decision about whether to include a Don't Know or Unsure button needs to be based on the objective of each question however the general guidance is to avoid "Don't Know" as it potentially reduces the effective sample size.	No change.

5. Did the questions/question style provide you with the opportunity to give the appropriate answer?	Respondent feedback	Researcher reflection	Amended wording/question format
Initial questions about dysphagia screening did not give 1 respondent the opportunity "to get across" their stepwise approach to screening.	*"We at X (and I know Y are similar) have a step wise approach to screening/assessing dysphagia which I couldn't quite get across in the way the questions were asked. To give context we have a modified water swallow screen the Specialist Stroke nurses are trained to do in ED which allows the patients to have thin fluids ONLY (if passed) and NBM (if failed), then when they come to the Stroke ward the Dysphagia Trained Nurses (DTNs) carry out a more comprehensive dysphagia screening assessment. Which allows modification if necessary - then SLT picks up if dysphagia is identified. So I answered for the DTN assessment rather than the modified water swallow screen."*	Research team discussed going back to this respondent to ask whether it would be helpful to have an 'any other comments' box at the end of the survey to have the opportunity to capture these and other kinds of variations that the existing questions don't allow for. The way the question is currently structured meets the question objective which was to find out what IDDSI levels are included in the dysphagia screen and what IDDSI level is used first. In the absence of a response from the respondent an additional question was added.	The following question gives you the opportunity to tell us about any other variations in dysphagia screening, assessment and management during the first 7 days of a patient's admission to your stroke unit.
Q25 How applicable are the following reasons for delays in stroke patients receiving a clinical (bedside) assessment in your stroke unit?	*"I would phrase it [Receiving late referrals in the working day] to 'Receiving referrals late in the working day', and 'poor communication that the patient requires SLT assessment' (rather than documentation –[Poor*	Research team agreed to change the wording to the suggested amendments.	Receiving referrals late in the working day Poor communication that the patient requires an SLT assessment

5. Did the questions/question style provide you with the opportunity to give the appropriate answer?	Respondent feedback	Researcher reflection	Amended wording/question format
	documentation that the patient requires an SLT assessment])		
Q26 Does your stroke unit have access to the following instrumental assessments of swallowing?	*"Although we had access to VF – this was not within our trust or area – we could only refer to X. For this reason, it wasn't largely used due to difficulties with waiting times, and patient suitability to travel that far e.t.c. Would it be appropriate to specify here whether there is 'in house' access to the services? One respondent who worked in stroke rehab commented*	The research team discussed this feedback in context of the question objective and that the respondent did not work in an Acute Stroke Unit.	It was agreed that it was not necessary to include "in house".
Q 27 Does your stroke unit use Videofluoroscopy within the first 7 days of a patient's admission?	*"I felt that I wanted to give some more detail as I answered Yes but I didn't want it to be interpreted that we do use it regularly with all patients within 7 days. We CAN use VF and do occasionally but we don't often use it so early. I think other people would answer the same but I don't think its used that frequently, that early. Is there a way to ask how often VF is used within 7 days to gauge its use?"*	For consistency it was agreed to add the word 'routinely' into Q27 and Q28 as per Q29. Wording of Q27, 28 and 29 was also amended e.g. "For those patient's where it is clinically indicated….	For those patients where it is clinically indicated, would your stroke unit **routinely** use Videofluoroscopy within the first 7 days of a patient's admission?

5. Did the questions/question style provide you with the opportunity to give the appropriate answer?	Respondent feedback	Researcher reflection	Amended wording/question format
Q 39 Does your stroke unit have a written oral care protocol?	*"There is a hospital oral care pathway which is used in stroke but not a specific one for stroke patients. I suspect this might be similar across other hospitals - perhaps you could give an option to state that in this question.* *There are protocols/pathways and there is practice. I know there is a big disparity as to what is on the oral care pathway vs what happens in practice. And there is real variability between staff in what is offered. I guess you wanted to know what happens in practice rather than what is in the protocols but maybe you can make that more explicit. Maybe you have ... I was going to go back and have a look at the questions to check whether they are clear on practice vs protocol but I didn't want to answer them again in case that skews your pilot."*	The research team agreed that the objective was to find out about practice (Q49) but also whether there is a written protocol similar to dysphagia screening and NGT standardisation. The research team also reverted to the statistical analysis of the question. It was collectively agreed the question was already explicit.	
	"Does this mean specific to the Unit, or can it be a hospital wide policy that should be used? We have a hospital wide policy and the unit is looking at putting something specific	An additional question was created.	Is this protocol a hospital oral care protocol or a specific protocol written for the oral care of stroke patients on your unit?

5. Did the questions/question style provide you with the opportunity to give the appropriate answer?	Respondent feedback	Researcher reflection	Amended wording/question format
	in place. I'm not sure if they are using it as there is a lot going on now about Mouthcare Matters. So I wasn't sure how to answer."		
Q 32 In patients who are unable to maintain adequate nutrition and fluids orally, please indicate typically the number of hours until an NGT is inserted	*"I found some of the options too specific, for example – the number of hours before NG tube inserted – this is dependent on several factors and will therefore vary between patients (could it be 0-6 hours, 6-12 etc) – also the position for feeding – the policy is for anything over 30 degrees, and so I put 30 degrees but this didn't feel quite right."* *"I think all of these points are fair comments - it is a guess for almost everyone, in the absence of a recent audit. Hopefully, giving options of time categories (as below) will make this seem less hard-core quantitative and more of a guesstimate based on intervals which have some reference point to what happens on the unit"*	The researcher had deliberately avoided using broad categories. It was subsequently decided to revert to categories.	Q32 In patients who are unable to maintain adequate nutrition and fluids orally, please indicate typically the number of hours from when the decision is taken to non orally feed and the beginning of feeding by an NGT? <6 hours ≥6-<12 hours ≥12-<24 hours ≥24-<48 hours
Q 38 What is the standard position in which the patient is positioned during NGT	*"For me, this bit about positioning for NGT feeding could be a bit confusing depending on your*	The researcher had deliberately avoided using broad categories. It	Q38 "Where 0 degrees is lying flat and 45 degrees is sat upright what is the standard

5. Did the questions/question style provide you with the opportunity to give the appropriate answer?	Respondent feedback	Researcher reflection	Amended wording/question format
feeding? Please select the angle between 0-90 degrees	*reference point (lay flat or sat upright!!). If sat upright as reference, then you mean the angle >90 and <180 from the sat upright position (as 90 degrees), where 180 degrees is lay flat? Otherwise, you mean x degrees from lay flat, where lay flat is zero. Needs to be clear (although maybe it will be to everyone else), and categories again probably more useful as unlikely you'd have a specific integer/figure in your head when answering"*	was subsequently decided to revert to categories.	position in which the patient is positioned during NGT feeding?" 0 degrees 0 - <30 degrees ≥ 30 <45 degrees 45 degrees Other (please state)
Q 49 What does oral care typically involve on the stroke unit? Please tick all that apply?	*"Should probably add in:* *brushing of dentures with water and/or soap* *soaking of dentures overnight in water"*	Additional statements were added although there was acknowledgement that the list of choices was already long so the response mechanism was changed to a yes/no for each option from 'tick all that apply' due to risk of primacy effects with long lists/visual presentation, and the possible effect on respondent behaviour i.e. people tend to choose their answers from the top of the list.	Brushing of dentures with water Brushing of dentures and cleaning with soap Soaking of dentures overnight in water

6. Were there any other issues that posed problems?	Respondent feedback	Researcher reflection	Amended wording/question format
Q 6 Is it mandatory that the person carrying out the dysphagia screen has been trained to use the dysphagia screening protocol?	*"You ask what professional groups are involved with swallow screening but not about any specific training they are required to complete before doing this – I wonder whether this would be worth adding – theory/ practical/ theory and practical?"*	The researcher felt this was an interesting comment although not directly relevant to question objectives and referenced previous discussions in supervision about training and filtering out questions that cannot be matched with a question objective or do not have a role in the analysis plan.	Research team agreed not the focus of the survey potential for future research.
Progress bar	*"Very minor issue this - the progress bar seemed to stick at around 60% from the last few pages - making me feel it might be a longer survey than in the end it was - jumped to 100% on the last page."*	The researcher investigated this issue with technical support.	No further action
Hospital drop down menu	*"Where we are asked to type in the name of the hospital we are responding from and then select from the drop down menu, the drop down listing doesn't appear"*	The researcher followed up this comment with the respondent and identified that the person had typed in an alternative name for the hospital. The names in the dropdown menu were based on what the hospitals in England and Wales are called on the SSNAP database. There was the facility for people to type in a name in the free text field, if the name they typed in did not appear in the drop-down menu.	No further action
Going back to a previous question	*"I can't seem to go back to this question."*	Not being able to go back on a question which is part of a survey flow is a function of the Qualtrics software and cannot be changed.	No further action

Other feedback	Respondent feedback	Researcher reflection	
Q 15 If the dysphagia screen identifies a dysphagia, is the patient referred for a clinical (bedside) swallowing assessment carried out by an appropriately trained healthcare professional?	*"From my own experience the answer might be yes but this is done so inappropriately, e.g. a failed swallow screen is then sent home to eat and drink normally and wait follow up in the community. Of course, you will know what you are trying to capture."* *"I have ticked yes, but in our unit, we ask for 3 screens within 24 hours if possible, to screen out patients who may be changing quickly, or improving from thrombolysis. We have been trying to do an audit to see if we can do away with the 3rd one (i.e. work out how many actually pass the 3rd one), in practice we may see them if they have had only 2 screens, especially on a Friday (we have Sunday weekend working) and also, when Ben Bray's work came out about the increase risk of SAP with increased delay, this did make us think about this. However, we also feel that by waiting a bit longer, we may be screening out people who don't need to see us and hence freeing us up to see those who are dysphagic. Also, I did ask around about this a bit before and some units said they would ask for another screen, so it may be worth putting in another option of: needs to fail screen more than once?? But entirely up to you."*	The research team agreed that respondent needs to raise this internally regarding the potential risk to patient safety. The Director of Studies was aware that this respondent had raised this and other issues internally. It was felt these variances would be captured by Q51 The following question gives you the opportunity to tell us about any other variations in dysphagia screening, assessment and management during the first 7 days of a patient's admission to your stroke unit.	No further action
Participant information sheet:	*Very clear, well set and explained clearly* *Very minor suggestion- on the last page (see below), one could set these out as bullet points as it reads more easily in the box* *Also very minor point, on the last page, instead of: Many thanks for considering to participate in this study. it may read better to say: Many thanks for considering participation in this study*		Bullet points were inserted.

Other feedback	Respondent feedback	Researcher reflection	
Q 45. Which staff group typically provide oral care? Please indicate if more than one group provide oral care.	*"We usually use a band 6 nurse and above, or an experienced band 5 nurse. Could you specify bandings for registered nurses perhaps? As for our screen, we would want to choose registered nurse (experienced and stroke nurse specialist)."*	The researcher revisited the rationale for the categories and felt it was not appropriate to break down the categories any further.	No further action
General comments	*"Overall the survey was user friendly, clear and well presented. I quickly worked my way through the answers this morning and made some notes on any issues I came across."* *"I like the format, it was clear and easy to use. I can really see the relevance of the survey whilst completing it. It doesn't feel overly long and I didn't get annoyed at any of the questions which I usually do when completing surveys. I'm looking forward to the results!" … Anyway - its a nice survey - I think you will get a good response. I can't wait until the results, it's really important research! "* *"Generally I think it is great, I do have a couple of comments"* *"It's looking great!! It's very user friendly and well set out."*		

Appendix F - Published electronic version of the survey "Dysphagia Screening, Assessment and Management in Acute Stroke"

Dysphagia Screening, Assessment and Management in Acute Stroke

Start of Block: Introduction

Q1 **How does variation in assessment and management of dysphagia in acute stroke affect the development of stroke-associated pneumonia (SAP)?** We would like to invite you to take part in the following survey. The survey will explore assessment and management of dysphagia and other clinical processes during the first seven days of person's admission to hospital following a stroke. The responses from the survey will be statistically analysed against data reported on the Sentinel Stroke National Audit Programme (SSNAP) database to identify factors which increase the risk of developing SAP in acute stroke. We understand that there may have been changes in clinical practice because of the COVID-19 pandemic. When answering the survey questions please tell us about what was happening before the start of the pandemic. Before you decide whether you wish to proceed, it is important you understand what the study is investigating and what it will involve. Please read the Participant Information Sheet and consider whether you wish to take part. By completing and submitting the survey, you will be providing consent for the data to be included in the final analysis. If you see an information symbol **ℹ** by the side of the question, this means there is further information to help you answer the question. Please hover your mouse over the question to see the additional information.

Q2 Are you a Speech and Language Therapist working in a National Health Service (NHS) hospital stroke unit in England or Wales?

- ○ Yes. I confirm I am a Speech and Language Therapist working in a NHS hospital stroke unit in England or Wales. I have read the participation information sheet and give consent for the information I provide to be used for research purposes. (1)
- ○ No. I am sorry you are not eligible to complete this survey. You will be re-directed to the final page of the survey (2)

Skip To: End of Survey If Are you a Speech and Language Therapist working in a National Health Service (NHS) hospital strok... = No. I am sorry you are not eligible to complete this survey. You will be re-directed to the final page of the survey

End of Block: Introduction

Start of Block: Name of Hospital

JS

Q3
Please type the name of your Hospital and select it from the drop down menu. If you are responding on behalf of more than one team, for example St. George's Hyper Acute Stroke Unit (HASU) and St. George's Stroke Unit (SU), you will need to complete the survey separately for each hospital team.

_____

End of Block: Name of Hospital

Start of Block: Dysphagia Screening

Q4 Does your stroke unit use a written dysphagia screening protocol?

- Yes (1)
- No (2)

Skip To: Q8 If Does your stroke unit use a written dysphagia screening protocol? = No

Q5 Is the dysphagia screen a screen that was developed by your hospital, or a published dysphagia screen? **i**

- Hospital dysphagia screen (1)
- Published dysphagia screen (2)

Q6 Is it mandatory that the person carrying out the dysphagia screen has been trained to use the dysphagia screening protocol?

- Yes (1)
- No (2)

Display This Question:

If Is the dysphagia screen a screen that was developed by your hospital or a standardised dysphagia... = Published dysphagia screen

Q7 Which published dysphagia screen is used?

_____

Skip To: Q13 If Condition: Which published dysphagia s... Is Displayed. Skip To: Which healthcare professional typical....

Q8 Are the following involved in the dysphagia screening protocol? (If your stroke unit does not have a written protocol, please indicate if any of the following are involved when screening patients for dysphagia).

- ○ Indirect swallowing test - *An indirect swallowing test may include checking the patient: is alert; can cough or clear their throat; is able to swallow their saliva successfully; checking for drooling of saliva or if the patient's voice has changed.* (1)
- ○ Oro-motor test (2)
- ○ Indirect swallowing test AND Oro-motor test (3)
- ○ Neither of the above (4)

Q9 Does the dysphagia screening protocol only use water (Level 0 Thin Fluids) i.e. 100% water?

- ○ Yes (1)
- ○ No (2)

Skip To: Q10 If Does the dysphagia screening protocol only use water (Level 0 Thin Fluids) i.e. 100% water? = Yes

Display This Question:

If Does the dysphagia screening protocol only use water (Level 0 Thin Fluids) i.e. 100% water? = Yes

Q10 What is the maximum amount of water given? Please indicate the maximum amount in millilitres (mls). For example, a single teaspoon is approximately 5 mls, therefore if the maximum amount given is 5 teaspoons select 25 mls.

▼ 5 (4) ... 200 (414)

Display This Question:

If Does the dysphagia screening protocol only use water (Level 0 Thin Fluids) i.e. 100% water? = No

Q11 Which International Dysphagia Diet Standardisation Initiative (IDDSI) levels are included in the dysphagia screening protocol?

- ☐ Level 0 Thin (1)
- ☐ Level 1 Slightly Thick (2)
- ☐ Level 2 Mildly Thick (3)
- ☐ Level 3 Moderately Thick (4)
- ☐ Level 4 Puree (5)
- ☐ Level 5 Minced and Moist (6)
- ☐ Level 6 Soft & Bite Sized (7)
- ☐ Level 7 Regular Easy to Chew (8)
- ☐ Level 7 Regular (9)

Display This Question:

If Does the dysphagia screening protocol only use water (Level 0 Thin Fluids) i.e. 100% water? = No

Q12 Which IDDSI level consistency do you screen with **first**?

- ○ Level 0 Thin (1)
- ○ Level 1 Slightly Thick (2)
- ○ Level 2 Mildly Thick (3)
- ○ Level 3 Moderately Thick (4)
- ○ Level 4 Pureed (5)
- ○ Level 5 Minced & Moist (6)
- ○ Level 6 Soft & Bite Sized (7)
- ○ Level 7 Regular Easy to Chew (8)
- ○ Level 7 Regular (9)

Q13 Which healthcare professional typically carries out the dysphagia screen? Please specify if more than one healthcare professional group is involved.

- ☐ Stroke Nurse Specialist (1)
- ☐ Registered Nurse (2)
- ☐ Nursing Associate/Apprentice (3)
- ☐ Non registered staff e.g. Clinical Support Worker, Healthcare Assistant (4)
- ☐ Other - Please specify (5) _____

Q14 Below is a list of reasons for **delays** in stroke patients being screened for dysphagia. How applicable are each of these reasons for delays in stroke patients being screened for dysphagia in your stroke unit?

	Strongly applicable (1)	Somewhat applicable (2)	Somewhat less applicable (3)	Strongly not applicable (4)
Lack of trained staff to screen patients in the Emergency Department (1)	○	○	○	○
Time management of the health professional responsible for screening (2)	○	○	○	○
Lack of awareness of the National Guidelines about screening patients for dysphagia (3)	○	○	○	○
Multiple admissions at the same time where the screen may be deprioritised if another patient requires medical intervention (5)	○	○	○	○
No designated screener responsible for screening and checking patients have been screened (6)	○	○	○	○
Delayed admission to a stroke bed (7)	○	○	○	○
The dysphagia screen may be deprioritised over other stroke tests (8)	○	○	○	○

If there are OTHER reasons that delay screening, please state what they are (9)	○	○	○	○

Q15 If the dysphagia screen identifies a dysphagia, is the patient referred for a clinical (bedside) swallowing assessment carried out by an appropriately trained healthcare professional?

- ○ Yes (1)
- ○ No (2)

Skip To: End of Block If If the dysphagia screen identifies a dysphagia, is the patient referred for a clinical (bedside)... = Yes

Display This Question:

If If the dysphagia screen identifies a dysphagia, is the patient referred for a clinical (bedside)... = No

Q16 If the patient is not referred for a specialist clinical (bedside) swallowing assessment which health professional group continues to review the patient's swallowing problem after the dysphagia screen? Please specify if more than one health professional group is involved.

- ☐ Stroke Nurse (1)
- ☐ Registered Nurse (2)
- ☐ Nursing Associate/Apprentice (3)
- ☐ Non registered staff e.g. Clinical Support Worker, Healthcare Assistant (4)
- ☐ Other - Please specify (5)

_____

End of Block: Dysphagia Screening

Start of Block: SLT Swallow Assessment (1/2) - Unskipped

Q17 Which healthcare professional typically carries out the clinical (bedside) swallowing assessment? Please indicate if more than one professional group is involved.

- ☐ Speech and Language Therapist (SLT) (1)
- ☐ Not a SLT but an autonomous Health Professional trained at Specialist Level (as defined by the Inter-Professional Dysphagia Framework) (2)

Q18 Does the stroke unit use a published dysphagia assessment for the clinical (bedside) swallowing assessment?

- ○ Yes (1)
- ○ No (2)

Display This Question:

If Does the stroke unit use a published dysphagia assessment for the clinical (bedside) swallowing a... = Yes

Q19 Please state what published assessment is used e.g. The MANN Assessment of Swallowing Ability (MASA).

_____

Skip To: Q25 If Condition: Please state what published... Is Displayed. Skip To: The following reasons have been ident....

Q20 Do you use written guidelines about what should be included in a clinical (bedside) swallowing swallow assessment?

- ○ Yes - The MANN Assessment of Swallowing Ability (MASA) (1)
- ○ Yes - Not the MANN but other guidelines. Please describe what is used. (2)

_____

- ○ No (3)

Q21 In your Stroke Unit, what does the first clinical (bedside) swallow assessment typically involve? Please tick all that apply.

- ☐ Previous medical history (1)
- ☐ History of presenting complaint (2)
- ☐ Assessment of cognitive-communication status (3)
- ☐ Assessment of respiratory status (9)
- ☐ Cranial nerve examination (4)
- ☐ Cough reflex testing (10)
- ☐ Assessment with oral intake (5)
- ☐ Assessment with postural techniques (6)
- ☐ Assessment with swallowing manoeuvres (7)
- ☐ Other - Please describe (8)

_____

Q22 What International Dysphagia Diet Standardisation Initiative (IDDSI) levels are **typically** included in the first clinical (bedside) swallow assessment?

- ☐ Level 0 Thin (1)
- ☐ Level 1 Slightly Thick (2)
- ☐ Level 2 Mildly Thick (3)
- ☐ Level 3 Moderately Thick (4)
- ☐ Level 4 Puree (5)
- ☐ Level 5 Minced and Moist (6)
- ☐ Level 6 Soft & Bite Sized (7)
- ☐ Level 7 Regular Easy to Chew (8)
- ☐ Level 7 Regular (9)

Display This Question:

If In your Stroke Unit, what does the first clinical (bedside) swallow assessment typically involve?... = Assessment with postural techniques

Q23 Please describe what postural techniques are assessed? **i**

_____

Display This Question:

If In your Stroke Unit, what does the first clinical (bedside) swallow assessment typically involve?... = Assessment with swallowing manoeuvres

Q24 Please describe what swallowing manouevres are assessed? **i**

_____

Q25 Below is a list of reasons for **delays** in stroke patients receiving a clinical (bedside) swallowing assessment. How applicable are each of these reasons for delays in stroke patients receiving a clinical swallowing assessment in your stroke unit?

	Strongly applicable (1)	Somewhat applicable (2)	Somewhat less applicable (3)	Strongly not applicable (4)
Lack of 7 day working by SLTs (1)	○	○	○	○
Insufficient number of SLTs (2)	○	○	○	○
Receiving referrals late in the working day (3)	○	○	○	○
Poor communication that the patient requires an SLT assessment (4)	○	○	○	○
Delays in onward referral following the dysphagia screen (5)	○	○	○	○
If there are OTHER reasons that delay assessment, please state what they are (6)	○	○	○	○
If there are OTHER reasons that delay assessment, please state what they are (7)	○	○	○	○

End of Block: SLT Swallow Assessment (1/2) - Unskipped

Start of Block: SLT Swallow Assessment (2/2) - Skipped

Q26 Does your stroke unit have access to the following instrumental assessments of swallowing?

- ○ Videofluoroscopy (VFS) (1)
- ○ Fibreoptic Endoscopic Evaluation of Swallowing (FEES) (2)
- ○ Both VFS and FEES (4)
- ○ Neither VFS or FEES (3)

Skip To: Q30 If Does your stroke unit have access to the following instrumental assessments of swallowing? = Neither VFS or FEES

Display This Question:

If Does your stroke unit have access to the following instrumental assessments of swallowing? = Videofluoroscopy (VFS)

Q27 For those patients where it is clinically indicated, would your stroke unit **routinely** use Videofluoroscopy within the first 7 days of a patient's admission?

- ○ Yes (1)
- ○ No (2)

Display This Question:

If Does your stroke unit have access to the following instrumental assessments of swallowing? = Fibreoptic Endoscopic Evaluation of Swallowing (FEES)

Q28 For those patients where it is clinically indicated, would your stroke unit **routinely** use FEES within the first 7 days of a patient's admission?

- ○ Yes (1)
- ○ No (2)

Display This Question:

If Does your stroke unit have access to the following instrumental assessments of swallowing? = Both VFS and FEES

Q29 For those patients where it is clinically indicated, would your stroke unit **routinely** use these assessments within the first 7 days of a patient's admission?

	Yes (1)	No (2)
Videofluoroscopy (VFS) (1)	○	○
Fibreoptic Endoscopic Evaluation of Swallowing (FEES) (2)	○	○

Q30 During the first 7 days of a stroke patient's admission, what treatment options are typically recommended on your Stroke Unit? Please indicate all that apply.

- ☐ Diet and fluids modification (1)
- ☐ Frazier Water Protocol (2)
- ☐ Swallowing manouvres (3)
- ☐ Postural techniques (4)
- ☐ Sensory stimulation (5)
- ☐ Tube feeding (6)
- ☐ Oro-motor exercises (7)
- ☐ Pharmacological management (8)
- ☐ Electrical stimulation (9)
- ☐ Biofeedback (10)
- ☐ Other - Please describe (11) _____

End of Block: SLT Swallow Assessment (2/2) - Skipped

Start of Block: NGT feeding

Q31 Does your stroke unit have a written nasogastric tube (NGT) feeding protocol?

- ○ Yes (1)
- ○ No (2)

Q32 In patients who are unable to maintain adequate nutrition and fluids orally, please indicate typically the number of hours from when the decision is taken to non orally feed and the beginning of feeding by an NGT?

- ○ < 6 hours (1)
- ○ ≥ 6 - < 12 hours (3)
- ○ ≥ 12 - < 24 hours (4)
- ○ ≥ 24 - < 48 hours (169)

Q33 How does your stroke unit check the position of the NGT before starting feeding?

- ☐ pH testing of NGT aspirate (1)
- ☐ Chest radiography if no aspirate obtained or pH above recommended level (2)
- ☐ Routinely perform chest radiography (3)
- ☐ Other - please state (4)

_____

Q34 In cases of inadvertent NGT removal, does your stroke unit typically use any of the following management strategies? Please tick all that apply.

- ☐ Mittens (1)
- ☐ Nasal retention device e.g. nasal bridle (2)
- ☐ 1:1 staff:patient supervision (3)
- ☐ Other - please state (4)

_____

Q35 Does your stroke unit have a written protocol for the maximum number of times the NGT can be inserted?

- ○ Yes (1)
- ○ No (2)

Q36 In case of inadvertent NGT removal, what is the maximum number of times reinsertion of the NGT is attempted in any patient?

- ○ Once (1)
- ○ Twice (2)
- ○ Three times (3)
- ○ If more than three, please state how many (4)

_____

Q37 Are NGTs inserted overnight?

- ○ Yes (1)
- ○ No (2)

Q38 Where 0 degrees is lying flat and 45 degrees is sat upright, what is the standard position in which the patient is positioned during NGT feeding?

- ○ 0 degrees (1)
- ○ > 0 - < 30 degrees (2)
- ○ ≥ 30 - < 45 degrees (3)
- ○ 45 degrees (4)
- ○ Other (please state) (5)

_____

End of Block: NGT feeding

Start of Block: Oral care

Q39 Does your stroke unit have a written oral care protocol?

- ○ Yes (1)
- ○ No (2)

Skip To: Q41 If Does your stroke unit have a written oral care protocol? = No

Q40 Is this protocol a hospital oral care protocol or a specific protocol written for the oral care of stroke patients on your unit?

- ○ Hospital oral care protocol (1)
- ○ Stroke oral care protocol (2)

Q41 Are there differences in oral care provision for patients in the hyper/acute stroke unit compared to those patients in other parts of the stroke pathway?

- ○ Yes (1)
- ○ No (2)

Skip To: Q42 If Are there differences in oral care provision for patients in the hyper/acute stroke unit compared... = Yes

Skip To: Q43 If Are there differences in oral care provision for patients in the hyper/acute stroke unit compared... = No

Q42 How is oral care provision in the hyper/acute stroke unit different to that provided post acute phase stroke?

_____

Q43 Are there differences in oral care provision for patients with dysphagia?

- ○ Yes (1)
- ○ No (2)

Skip To: Q44 If Are there differences in oral care provision for patients with dysphagia? = Yes

Skip To: Q45 If Are there differences in oral care provision for patients with dysphagia? = No

Q44 If yes, please describe what differences there are in oral care provision for people with dysphagia compared to the provision for those people without dysphagia.

_____

Q45 How often each day is mouth care typically provided to people with dysphagia on the stroke unit?

- ○ Not at all (1)
- ○ Once (2)
- ○ Twice (3)
- ○ Three times (4)
- ○ Other - please state (5)

_____

Q46 Which staff group typically provide oral care? Please indicate if more than one group provide oral care.

- ☐ Registered Nurse (1)
- ☐ Nursing Associate or Nursing Apprentice (2)
- ☐ Non registered staff e.g. clinical support worker and healthcare assistants (3)
- ☐ SLT (4)
- ☐ Occupational Therapist (5)
- ☐ Other - please state (6) _____

Q47 Do staff receive training in oral care?

- ○ Yes (1)
- ○ No (2)

Skip To: Q48 If Do staff receive training in oral care? = Yes
Skip To: Q50 If Do staff receive training in oral care? = No

Q48 What type of training do staff receive?

- ☐ Ward based training (1)
- ☐ Classroom based training (4)
- ☐ Online training (2)
- ☐ Other - please describe (3) _____

Q49 Is the training staff receive specific to the oral care of stroke patients?

- ○ Yes (1)
- ○ No (2)

Q50 What does oral care typically involve on the stroke unit?

	Yes (24)	No (25)
Brushing of teeth and cleaning of gums with toothpaste (1)	○	○
Brushing of teeth and cleaning of gums with chlorhexidine dental gel (2)	○	○
Brushing of teeth and cleaning of gums using an electric toothbrush (3)	○	○
Brushing of teeth and cleaning of gums using a suction toothbrush (4)	○	○
Brushing of teeth and cleaning of gums with a manual toothbrush (5)	○	○
Removal of excess secretions (6)	○	○
Removal of dentures overnight (7)	○	○
Brushing of dentures with water (8)	○	○
Brushing of dentures and cleaning with soap (9)	○	○
Brushing of dentures and cleaning with toothpaste (10)	○	○
Brushing of dentures and cleaning with chlorhexidine dental gel (11)	○	○
Soaking of dentures overnight in dental cleaning solution (12)	○	○
Soaking of dentures overnight in water (13)	○	○
Application of lip balm (14)	○	○
Other - please describe (15)	○	○

Q51 The following question gives you the opportunity to tell us about any other variations in dysphagia screening, assessment and management during the first 7 days of a patient's admission to your stroke unit.

_____

Q52 Please let us know if you would be happy to share your Trust protocols relating to the screening, assessment and management of stroke patients with dysphagia.

- ○ Yes (1)
- ○ No (2)

End of Block: Oral care

Appendix G – Supplementary material for the survey results

Paper 5

Eltringham, S. A., Bray, B. D., Smith, C. J., Pownall, S. and Sage, K. (2021) 'Are Differences in Dysphagia Assessment, Oral Care Provision, or Nasogastric Tube Insertion Associated with Stroke-Associated Pneumonia? A Nationwide Survey Linked to National Stroke Registry Data.'

Itemised list of figures and tables:

a. Table 1 – Checklist for Reporting Results of Internet E-Surveys (CHERRIES)
b. Table 2 – Coefficient[a] Univariable analysis
c. Table 3 - Coefficient[a] Univariable analysis using the SSNAP Apr19Mar20 Patient Centred Post 72h cohort data
d. Table 4 - Coefficient[a,b] Univariable analysis excluding Greater Manchester and Cheshire, Thames Valley and Wales SCN regions
e. Figure 1: Published Dysphagia Screens by frequency and type
f. Figure 2: Typical oral care by frequency and type of intervention
g. Figure 3: Typical oral care for people with dentures by frequency and type of intervention

Available online https://karger.figshare.com/articles/dataset/Supplementary_Material_for_Are_Differences_in_Dysphagia_Assessment_Oral_Care_Provision_or_Nasogastric_Tube_Insertion_Associated_with_Stroke-Associated_Pneumonia_A_Nationwide_Survey_Linked_to_National_Stroke_Registry_Data/17212