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Screening for aspiration risk associated with dysphagia in acute stroke (Protocol)

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Screening for aspiration risk associated with dysphagia in acute stroke

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ABSTRACT

This is a protocol for a Cochrane Review (Diagnostic test accuracy). The objectives are as follows:

To determine the diagnostic accuracy of bedside screening tools for detecting dysphagia, which is a predictor of aspiration, in people with acute stroke.

To assess the influence of the following potential sources of heterogeneity.

- Patient demographics (e.g. age, gender, % of males in study, median age of study by gender).

- The time post-stroke that the study was conducted (from admission to 48 hours) to ensure only hyperacute and acute stroke dysphagia screening tools are identified.

- Any significant change in the patient's condition between the index and reference tests being performed.

- The definition of dysphagia used by the study.

- Level of training of nursing staff, both grade and training in the screening tool.

- Low quality studies identified from the methodological quality checklist.

- i) Type of the index test and ii) the threshold of the index test

- Type of the reference test

BACKGROUND

Stroke is the second most common cause of death and of adult disability worldwide (Murray 2013) and affects around 15 million people each year (Townsend 2012; WHF 2016). Stroke is the second or third leading cause of death in most countries, and the single largest cause of complex preventable disability in adults (National Audit Office 2005; WHF 2016). Dysphagia (i.e. difficulty swallowing) is a common sequelae following stroke and may lead to aspiration. Aspiration can be defined as food or fluid entering the airway below the level of the vocal cords, and into the trachea. It may, in some patients, precipitate pneumonia. Hence, aspiration is considered one of the most important consequences of dysphagia and is therefore the focus of this review. The reported incidence of dysphagia following acute stroke varies from 39% (Odderson 1995) to approximately 50% (Mann 2000; Martino 2005). Studies report that the prevalence of dysphagia varies according to stroke subtypes, and may lead to adverse health outcomes ranging from hospitalisation to death (Mann 2000; Smithard 1996). Pneumonia is reported in 16% of all people admitted with a stroke and is a significant cause of morbidity post-stroke (Intercollegiate Stroke Working Party 2012). In addition, dysphagia can result in secondary effects such as reduced stamina, increased likelihood of pressure sores, reduced physical recovery, reduced wound healing, and increased risk of anxiety or depression (Marks 2001). Early identification of dysphagia may help to avoid such adverse health outcomes (Donovan 2013). Current clinical guidelines within the UK, Europe, Canada, the USA, and Australia state that on admission to hospital, people with acute stroke should have their swallowing screened within four hours of admission to hospital by a trained healthcare professional prior to being given any oral food, fluid or medication (Intercollegiate Stroke Working Party 2012; Murray 2013; NICE 2008). There is currently variation in adherence to guidelines (14% to 79%) (Murray 2013; RCP 2014). Moreover, the identification of a gold standard screening tool that meets the needs of all patients is made more difficult owing to the complexity and variability of the normal swallow within and between individuals and the adaptation and compensation evident in stroke patients with dysphagia. Unfortunately, significant limitations apply to the gold standards / reference tests, rendering them inappropriate for some people in the acute stages of stroke. Limitations may be patient specific (patients may be unable to comply with instructions due to poor posture, cognition, or medical state); organisational limitations (not all staff are trained to undertake or interpret the results of the reference test); or procedural (specialist equipment is not available in all acute settings).

In clinical practice, bedside swallow screening tools are used by health professionals to identify patients at risk of dysphagia, and aspiration, following acute stroke (Intercollegiate Stroke Working Party 2012). There are many index tests that vary in the types of food and fluid tested. Water swallow tests e.g. standardised swallow assessment (Perry 2001); Massey Bedside swallow screen (Massey 2002), offer people different quantities of fluids with different utensils. These tests fail to address difficulties in swallowing food, and therefore, people are prohibited from eating or drinking until a more specialist assessment is undertaken. However, a more specialist assessment (Fibreoptic Endoscopic Evaluation of Swallowing) has shown that these restrictions may result in unnecessary restrictions of food and fluid intake in a proportion of patients (Suiter, 2008). On the other hand, a screening tool that included a range of consistencies e.g. Gugging Swallow Screen (Trapl, 2007), was tested in a who, despite being unusually able (conscious, cognitively able and postural control, and able to co-operate with the assessment) were also suspected as having swallowing problems. Following identification of dysphagia by the bedside swallow screening tool, the person is referred for a further specialist bedside swallow assessment by a speech and language therapist to identify the stage of swallowing difficulties, and devise management plans. In order to be clinically useful, a screening tool needs to accurately identify those with dysphagia, with its associated risk of aspiration, (sensitivity) without leading to unnecessary restrictions, i.e. 'nil by mouth' (the withholding of oral intake of food and fluid), in those who do not have dysphagia (specificity). The analysis is a binary evaluation (aspiration present or not) although it is acknowledged that there may be different levels of severity of swallowing difficulty and subsequent management. It also needs to be acceptable and feasible for use in people with a range of sequelae following stroke, e.g. different levels of consciousness, cognitive levels, and postural difficulties.

The lack of a universally acceptable screening tool for identification, and management of aspiration, associated with dysphagia, has meant that many screening tools used in clinical practice have evolved throughout the world. Hence, there is a need to find clinically useful screening tools that will correctly identify the presence or absence of aspiration associated with dysphagia, allowing appropriate management to be prescribed for those individuals with aspiration in order to improve patients' medical, social, and psychological outcomes.

Target condition being diagnosed

People who have aspiration risk associated with dysphagia following an acute stroke.

Index test(s)

Swallow screening tools used at the bedside by healthcare professionals i.e. nursing staff, for the recognition or the determination of whether the patient has dysphagia. These should be predictors

of whether the patient is at risk of aspiration. Current practice dictates that screening tool findings determine whether the patient is kept nil orally; however, unnecessary nil by mouth, due to low specificity, may have adverse effects on quality of life, whereas low sensitivity of a swallow screen may allow inappropriate patients to proceed to oral intake, thereby precipitating hospital acquired pneumonia.

Identification of a diagnostically accurate tool could lead to more clinically-focused treatment, resulting in improved patient outcomes.

Clinical pathway

The clinical pathway for patients who are at risk of aspiration commences upon their admission to hospital, where they should be assessed within a maximum of four hours for their ability to swallow, using a validated swallow screening test (index test) administered by an appropriately trained person. This must take place prior to the patient being offered any oral food, fluid or medication. People who are unable to take adequate nutrition and hydration orally should be considered for clinically assisted nutrition and hydration within 24 hours of admission and referred to an appropriately trained healthcare professional for detailed nutritional assessment, individualised advice and monitoring. People with dysphagia should be given food, fluids and medication in a form that can be swallowed without aspiration following a specialist assessment of swallowing (Murray 2013; WHO 2014).

Prior test(s)

No tests to assess swallowing are conducted on patients prior to hospital admission.

Role of index test(s)

Screening tools have the potential to improve the identification of people with a risk of aspiration associated with dysphagia following stroke. Therefore, they may reduce the need for more complex, invasive and more expensive imaging methods e.g. videofluoroscopy (VFS); fibreoptic endoscopic evaluation of swallowing (FEES) or scintigraphy.

Alternative test(s)

Other tests that include questionnaires that rely on self-reported dysphagia symptoms. However, these tools e.g. Sydney foods of different viscosities Swallow Questionnaire (SSQ), The Swallowing Disturbance Questionnaire (SDQ) were used or designed and validated for use in different patient populations e.g. head and neck cancer, and Parkinson's disease.

Rationale

We will review the diagnostic accuracy of currently available dysphagia screening tools. A systematic review of published evaluations of these screening tools will assist practitioners to identify ones that have undergone rigorous development (or similar). The review will also identify gaps in evidence for further research.

Healthcare professionals within acute stroke care settings are responsible for deciding which bedside swallow screening tool they will use for detecting people at risk of aspiration associated with dysphagia in adult acute stroke patients. When considering a bedside swallow screening tool, a test with high sensitivity and specificity is paramount. False negative results may lead to continued oral intake that may precipitate aspiration pneumonia. High specificity is also necessary as false positive results impact on patients being placed nil by mouth with clinically assisted nutrition and hydration unnecessarily, thereby adversely affecting the wellbeing of patients and incurring unnecessary costs.

The Intercollegiate Stroke Working Party 2012 recommends that all patients should have their ability to swallow tested, using a bedside swallow screening tool, within four hours of admission to hospital in view of the potential reduction in aspiration and subsequent effect on poor patient outcome.

Systematic reviews of bedside swallow screening tools to date have provided descriptive analysis of the different elements within screening tools with no defined reference test (Almeida 2015). Other reviews have either: not specifically focused on a stroke population (Brodsky 2016; O'Horo 2015); have considered studies not undertaken in a timely manner (Schepp 2012); have focused on individual clinical determinants, or behaviours associated with aspiration (Daniels 2012), or accepted delays of over 24 hours between the index test and the reference standard (Daniels 2012). The results of this review will help to guide policy makers and healthcare workers in acute hospital settings on the appropriate bedside swallow screening tools that are currently available.

O B J E C T I V E S

To determine the diagnostic accuracy of bedside screening tools for detecting dysphagia, which is a predictor of aspiration, in people with acute stroke.

Secondary objectives

To assess the influence of the following potential sources of heterogeneity.

● Patient demographics (e.g. age, gender, % of males in study, median age of study by gender).

● The time post-stroke that the study was conducted (from admission to 48 hours) to ensure only hyperacute and acute stroke dysphagia screening tools are identified.

- Any significant change in the patient's condition between the index and reference tests being performed.
- The definition of dysphagia used by the study.
- Level of training of nursing staff, both grade and training in the screening tool.
- Low quality studies identified from the methodological quality checklist.
- i) Type of the index test and ii) the threshold of the index test
- Type of the reference test

METHODS

Criteria for considering studies for this review

Types of studies

Sensitivity, specificity and diagnostic accuracy: we will include and consider separately single-gate (cohort study) and two-gate (case control study) designs in which the bedside screening tools administered by nursing staff are compared against expert assessment (dysphagia trained professionals i.e. speech and language therapists. Expert assessment is included owing to the lack of immediate access to imaging / instrumental assessment in many centres, and to the inability of some patients to co-oprate with these imaging / instrumental assessments. The endpoint of the reference tests will be defined as aspiration. Aspiration is defined as the entry of material below the level of the vocal cords. Studies which introduce delay of greater than 24 hours between the index and reference measurement may introduce bias because of the potential changes in patient consciousness and cognitive status; we will not exclude these studies from the review, but will assess the potential for bias before including them in the analyses.

We will identify any studies where the 2x2 tables have not been obtained by allocating the population to the four cells in the table (for example they have chosen a number who test positive and see if they have the condition, and then choose the same number who test negative and then see if they have the condition) and analyse them accordingly as they will use different formulae to calculate sensitivity and specificity.

Participants

Inclusion criteria: We will include only full text papers that include people (aged 18 and above) who have been admitted to an acute hospital setting, where there is a clinical diagnosis of stroke. We will consider papers that are inclusive of people with subarachnoid haemorrhage and will exclude analysis of this sample subgroup where possible.

Exclusion criteria: We will exclude those full text papers that include patients exclusively with subarachnoid haemorrhage. Patients admitted with trauma will be excluded from the study.

Index tests

Swallow screening tools (for use at the bedside) by healthcare professionals for the recognition or the determination of whether the patient is at risk of aspiration associated with dysphagia.

Target conditions

Aspiration owing to dysphagia post-stroke.

Reference standards

- Expert assessments - dysphagia trained professionals. Expert assessment - dysphagia trained professionals i.e. speech and language therapists. Expert assessment is included owing to the lack of immediate access to imaging/ instrumental assessment in many centres, and to the inability of some patients to co-operate with these imaging/instrumental assessments.
- VFS, which is a X-ray video of swallowing, allowing the swallow to be analysed in real time.
- FEES, which involves insertion of a fibreoptic flexible endoscope to be passed through the nasal passages to view the throat pre- and post-swallows for secretion management, residue and aspirated material.
- Scintigraphy uses radioisotopes that are swallowed and the emitted radiation is captured by external detectors (gamma cameras) to form images of swallowed material and a tracheal pH probe is inserted into the airway under local anaesthetic and maintained in position to assess alteration in pH following aspiration of material into the airway.

Search methods for identification of studies

We will search relevant bibliographic databases from the earliest year possible to the present. We developed the MEDLINE search strategy with the help of the Cochrane Stroke Group Information Specialist and will adapt it for other databases (Appendix 1). We will not impose any restrictions in terms of language of publication.

Electronic searches

We will search the following electronic bibliographic databases.
- Cochrane Central Register of Controlled Trials (CENTRAL) (Cochrane Library, latest issue)
- MEDLINE (Ovid) (from 1946) (Appendix 1);
- Embase (Ovid) (from 1980);
- CINAHL IN EBSCO (Cumulative Index to Nursing and Allied Health Literature; 1937 onward);

- Health Technology Assessment Database (HTA) (Cochrane Library, latest issue)

Searching other resources

- We will search the references of relevant papers, included studies and any relevant systematic reviews;
- We will contact experts and authors for information about unpublished or ongoing studies, or systematic reviews in development, related to this review;
- We will perform a cited reference search using Science Citation Index for forward tracking of relevant articles;
- We will search grey and hard to find literature using appropriate websites e.g. greynet.org.

Data collection and analysis

Selection of studies

Three review authors (to be confirmed) will independently screen all titles and abstracts identified by the electronic database searches and exclude obviously irrelevant records. We will then obtain full text copies of the remaining studies, and the same authors (TBC) will independently review the papers using the criteria detailed in the methods section. Only papers where full-text can be obtained will be included. In case of differences of opinion on whether to include a particular study, a fourth review author (TBC) will serve as arbiter. To avoid double-counting, we will identify multiple publications based on the same cohort of patients and we will only select the study with the most complete and up to date data. If the publication does not present the data in a useable way then another publication with a large sample and useable data will be used. We will illustrate the selection process using the PRISMA flow diagram.

Data extraction and management

We will use a data abstraction form designed ad-hoc for the purpose of this review to collect details from the included studies. We will pilot the form on other diagnostic accuracy studies that are related to acute stroke management, but that fall beyond the scope of this review. The data extraction form will include information on the characteristics of the studies, the patient population and the relevant outcomes. Two review authors will independently extract the data to ensure adequate reliability and quality of the data. Our statistician will act as a third party to review the extraction of some of the data to further ensure quality and reliability.

Assessment of methodological quality

Two review authors will review the studies independently and classify them using the tools and systems described above. We will resolve any disagreements with a third review author.

The review will use the criteria from the QUADAS tool to assess the methodological quality of the studies selected for the systematic review, which are recommended by the Cochrane Collaboration (see Table 1).[Whiting et al, 2003; Reitsma et al, 2009] These will be rated as either 'yes', 'no' or 'unclear'. Guidance indicates that criteria 1, 2, 3 and 9 should receive particular attention regarding the definitions used as the basis for decisions. The other criteria are more self-explanatory with regards to their interpretation. Criteria 1: The population included within the systematic review has been defined in the selection criteria as non-trauma patients, aged 18 years and above, who have been admitted to an acute hospital setting with a clinical diagnosis of stroke (excluding subarachnoid haemorrhage). The definition of the participant population for inclusion represents those who would receive the test, allowing decisions regarding whether studies are appropriate and representative. This will allow clear decisions to be made as to whether the response to the criteria should be either 'yes', 'no' or 'unclear'. If the study being assessed includes only a limited subset of the specified population (e.g. people aged >75 years or only people with severe stroke), then it would be classified as 'no' on the criteria. The influence of such factors on test accuracy will be assessed within the synthesis through sub-group analysis or meta-regression. If insufficient information is provided to make judgements, it will be classified as 'unclear'. Criteria 2: Several reference standards have been identified for study selection, including speech and language therapists, VFS, FEES and scintigraphy. If one or more of these reference standards are used, the criteria will be assessed as 'yes'. If not it will be assessed as 'no' or 'unclear' if insufficient information is provided. Criteria 3: The systematic review will require that the reference standard and index tests should be undertaken within 24 hours of each other or the study gives an indication that the patient has not changed medically between the index and the reference test, to be reasonably sure that the target condition has not changed between the two tests, allowing the criteria to be classified as 'yes'. If the period between the two tests is longer it will be classified as 'no' and if insufficient information is provided it will be classified as 'unclear'. If only a proportion of the participants have met the criteria, the review will require ≥70% of participants to be tested with both the reference standard and index test in 24 hours to be classified as 'yes'. Criteria 9: Information regarding the characteristics of the patient (e.g. age, sex), the severity of their condition (e.g. time post stroke) and other tests may influence interpretation of either the reference standard or the index test. It will be important to ensure that the same information is available when both the tests were undertaken and that would be available in practice. If the study included basic information regarding the participant's characteristics and condition that would normally be collected as part of the patient assessment, then the criteria should

be classified as 'yes'. If either no information was obtained or additional information is collected as part of the study, then the criteria should be classified as 'no'. If insufficient information is provided it should be classified as 'unclear'.

We will use the skills of the Cochrane Stroke Group Information Specialist to help transfer the MEDLINE strategy to the other databases.

No language limits will be used.

Statistical analysis and data synthesis

From each primary study we will extract or derive the values to give the 2x2 table for the index test giving the true positives, false positives, true negatives and false negatives. From these we will calculate the sensitivities, specificities, and their 95% confidence intervals. Data from a single study will only be used once in each analysis.

We will plot coupled forest plots for all the studies used, showing the figures from the 2x2 table and the estimated sensitivity, and specificity. We will also plot a summary ROC that displays each study in ROC space, with the size or shape representing the precision or size of the study.

We expect that the studies used in this review will be of a varied nature and unlikely to use a common threshold. We will therefore carry out the analysis for test comparison using the Rutter and Gastonis HSROC model as this will allow us to use data from all relevant studies. If studies have more than one threshold only one will be selected based on which threshold has the highest sensitivity. The Rutter and Gastonis HSROC model will fit a summary ROC curve. The comparison of the tests can be made in ROC space, preferable thresholds may be observed and sensitivity deduced for a fixed specificity (or vice versa). Estimates of sensitivity AND specificity are not made using the HSROC model. For the modelling β, the shape parameter, is fitted as a fixed effect. θ, a representation of the threshold, and α, (=lnDOR) a measure of the test accuracy, are both random effects and assumed to be independent and normally distributed. Although it is expected that we will perform analysis for test comparison using the HSROC model, if the screening shows studies which have common thresholds then we would consider running a bivariate analysis. A study could contribute to the analysis of a given threshold if it reported at that threshold and could be included in more than one analysis. We will only perform this meta-analysis if there are sufficient numbers of studies, at least four per group. We will use Stata v14 StataCorp. 2014 and RevMan 5 (RevMan 2014) software.

Investigations of heterogeneity

As heterogeneity in the test accuracy is presumed to exist we will fit a random-effects model. As we are using the HSROC model we can also investigate the heterogeneity of the threshold. We will perform meta-regression by adding study level covariates to the model to investigate their influence on the heterogeneity of both test accuracy and threshold. These covariates are assumed to have a fixed effect. The covariates of interest are patient demographics (e.g. age, gender), the time post-stroke that the study was conducted, and the level of training of nursing staff. The definitions of dysphagia used by the study will be grouped. Average patient demographic profiles for each study will be used as an individual participant data (IPD) meta-analysis will not be performed. We may also investigate the type and quality of the reference test as well as the type of index test as sources of heterogeneity.

Sub-group analysis will be performed using age, gender, time post-stroke of the index test, index test type and if there has been a significant change in the patient's condition between the index and reference tests being performed.

The meta-regression can only be performed providing there are sufficient studies. If there are too few studies, we will perform only a narrative review running exploratory analysis in RevMan 5 to show graphically if the covariates of interest are likely to be related to the test accuracy (RevMan 2014). This will be displayed using forest plots and ROC plots.

Sensitivity analyses

We may carry out sensitivity analysis by excluding low quality studies, providing we have enough studies. We may exclude those where there is a delay in time between index and reference tests due to potential changes in patient consciousness and cognitive state, and compare the results with the full analysis.

We may identify other selection criteria for sensitivity analysis during the development of the review.

Assessment of reporting bias

As there are no methods to quantify publication bias in diagnostic test accuracy reviews we will not report on this.

ACKNOWLEDGEMENTS

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REFERENCES

Additional references

Almeida 2015

Almeida TM, Cola PC, Pernambuco LA, Magalhaes Jr HV, Silva RG. Screening tools for oropharyngeal dysphagia in stroke. *Audiology - Communication Research* 2015;**20**(4): 361–70.

Brodsky 2016

Brodsky MB, Suiter DM, Gonzalez-Fernandez M, Michtalik HJ, Frymark TB, Venediktov R, et al. Screening accuracy for aspiration using bedside water swallow tests: a systematic review and meta-analysis. *Chest* 2016;**150**(1):148–63.

Daniels 2012

Daniels SK, Anderson JA, Willson PC. Valid items for screening dysphagia risk in patients with stroke. *Stroke* 2012;**43**(3):892–7.

Donovan 2013

Donovan NJ, Daniels SK, Edmiaston J, Weinhardt J, Summers D, Mitchell PH. Dysphagia screening: state of the art: invitational conference proceeding from the State-of-the-Art Nursing Symposium, International Stroke Conference 2012. *Stroke* 2013;**44**(4):e24–31.

Intercollegiate Stroke Working Party 2012

Intercollegiate Stroke Working Party. National Sentinel Stroke Clinical Audit 2010. Royal College of Physicians 2012.

Mann 2000

Mann G, Hankey G, Cameron D. Swallowing disorders following acute stroke: prevalence and diagnostic accuracy. *Cerebrovascular Diseases* 2000;**10**(5):380–6.

Marks 2001

Marks L, Rainbow D. *Working with Dysphagia*. Oxford: Speechmark Publishing Ltd, 2001.

Martino 2005

Martino R, Foley N, Bhogal S, Diamant N, Speechley M, Teasell R. Dysphagia after stroke: incidence, diagnosis, and pulmonary complications. *Stroke* 2005;**36**(12):2756–63.

Massey 2002

Massey, R, Jedlicka, D. The Massey Bedside Swallowing Screen. *Journal of Neuroscience Nursing* 2002;**34**(5):252-3; 257-60.

Murray 2013

Murray CJ, Vos T, Lozano R, Naghavi M, Flaxman AD, Michaud C, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2013;**15**(380):2197–223.

National Audit Office 2005

National Audit Office. *Reducing Brain Damage: Faster Access to Better Stroke Care*. London: The Stationery Office, 2005.

NICE 2008

National Institute for Health and Clinical Excellence. *Stroke: Diagnosis and Initial Management of Acute Stroke and Transient Ischaemic Attack (TIA)*. London: NICE, 2008.

O'Horo 2015

O'Horo JC, Rogus-Pulia N, Garcia-Arguello L, Robbins J, Safdar N. Bedside diagnosis of dysphagia: a systematic review. *Journal of Hospital Medicine* 2015;**10**(4):256–65.

Odderson 1995

Odderson, I R, Keaton, J C, McKenna, B S. Swallow Management in Patients on an Acute Stroke Pathway: Quality is Cost Effective. *Arch Phys Med Rehabil.* 1995;**76** (12):1130–1133.

Perry 2001

Perry, L. Screening Swallowing Function of Patients with Acute Stroke: Rationale, Identification, implementation and Initial Evaluation of a Screening Tool for use by Nurses. *Journal of Clinical Nursing* 2001;**110**(4):463–473.

RCP 2014

Royal College of Physicians. National Sentinel Stroke Audit Phase 3 (clinical audit) 2013. Royal College of Physicians of London 2014.

RevMan 2014 [Computer program]

The Nordic Cochrane Centre, the Cochrane Collaboration. Review Manager (RevMan). Version 5.3. Copenhagen: The Nordic Cochrane Centre, the Cochrane Collaboration, 2014.

Schepp 2012

Schepp K, Tirschwell DL, Miller RM, Longstreth Jr WT. Swallowing screens after acute stroke: a systematic review. *Stroke* 2012;**43**(3):869–71.

Smithard 1996

Smithard DG, O'Neil PA, Parks C, Morris J. Complications and outcome after stroke. Does dysphagia matter?. *Stroke* 1996;**27**:1200–4.

StataCorp. 2014 [Computer program]

StataCorp. 2014.

Suiter, 2008

Suiter, D.M, Leder, S B. Clinical Utility of the 3-ounce Water Swallow Test. *Dysphagia* 2008;**23**(3):244–250.

Townsend 2012

Townsend N, Wickramasinghe K, Bhatnagar P, Smolina K, Nichols M, Leal J, et al. *Coronary Heart Disease Statistics 2012 Edition*. British Heart Foundation, 2012.

Trapl, 2007

Trapl, M, Enderle, P, Nowotny, M, Teuschl, Y, Matz, K, Dachenhausen, A, Brainin, M. Dysphagia Bedside Screening for Acute Stroke Patients: The Gugging Swallowing Screen. *Stroke* 2007;**38**:2948–2952.

WHF 2016

World Heart Federation. The global burden of stroke. www.world-heart-federation.org/cardiovascular-health/ stroke/ 2016.

WHO 2014

World Health Organization. Fact sheet Number 310: the top 10 causes of death 2012. World Health Organization, Media Centre 2014.

APPENDICES

Appendix 1. MEDLINE search strategy

MEDLINE (Ovid) (from 1946) (Date of Search: 26.01.2017)

1. cerebrovascular disorders/ or basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp cerebral small vessel diseases/ or exp intracranial arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or exp brain infarction/ or stroke, lacunar/ or vasospasm, intracranial/ or vertebral artery dissection/

2. (stroke$ or poststroke or apoplex$ or cerebral vasc$ or brain vasc$ or cerebr vasc$ or cva$ or SAH).tw.

3. ((brain or cerebr$ or cerebell$ or vertebrobasil$ or hemispher$ or intracran$ or intracerebral or infratentorial or supratentorial or middle cerebral artery or MCA$ or anterior circulation or posterior circulation or basilar artery or vertebral artery or space-occupying) adj5 (isch?emi$ or infarct$ or thrombo$ or emboli$ or occlus$ or hypoxi$)).tw.

4. ((brain$ or cerebr$ or cerebell$ or intracerebral or intracran$ or parenchyma or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli$ or putaminal or putamen or posterior fossa or hemispher$ or subarachnoid) adj5 (h?emorrhag$ or h?ematoma$ or bleed$)).tw.

5. hemiplegia/ or exp paresis/ or exp Gait Disorders, Neurologic/

6. (hemipleg$ or hemipar$ or paresis or paraparesis or paretic).tw.

7. or/1-6

8. Deglutition/

9. exp Deglutition Disorders/

10. ((swallow$ or deglutit$ or dysphag$) adj5 (disturbance$ or disorder$ or difficult$ or dysfunction$ or impair$ or condition$ or abnormal$ or damage$ or injur$)).tw.

11. Pharynx/ or pharyngeal muscles/ or esophageal sphincter, upper/ or exp Esophagus/

12. ((throat or oesophag$ or esophag$ or phar$ or oropharyn$) adj5 (disturbance$ or disorder$ or difficult$ or dysfunction$ or impair$ or condition$ or abnormal$ or damage$ or injur$)).tw.

13. exp Respiratory Aspiration/

14. ((inhal$ or aspirat$ or inges$) adj3 (scale$ or screen$ or checklist$ or assess$ or identif$ or recogni$ or evaluat$ or diagnos$ or detect$ or hazard or risk)).tw.

15. or/8-14

16. exp "Sensitivity and Specificity"/

17. diagnostic errors/ or false negative reactions/ or false positive reactions/ or observer variation/ or "diagnostic techniques and procedures"/

18. (sensitiv$ or specificity or distinguish$ or differentiat$ or enhancement or identif$ or detect$ or screen$ or test$ or assess$ or diagnos$ or accur$).tw.

19. exp "Sensitivity and Specificity"/

20. diagnosis/ or early diagnosis/

21. diagnostic errors/ or false negative reactions/ or false positive reactions/ or observer variation/ or "diagnostic techniques and procedures"/

22. (sensitiv$ or specificity or distinguish$ or differentiat$ or enhancement or identify$ or detect$ or screen$ or test$ or assess$ or diagnos$ or accur$).tw.

23. Predictive Value of Tests/

24. (predictive adj3 value$).tw.

25. (false adj3 (positive$ or negative$)).tw.

26. (receiver operat$ adj3 (characteristic$ or curve or analysis)).tw.

27. (ROC or SROC or HSROC).tw.

28. likelihood function/

29. (likelihood adj3 ratio$).tw.
30. or/19-29
31. 7 and 18 and 30

Appendix 2. QUADAS-2 tool: Risk of bias and applicability judgments

Domain 1: Patient selection		Domain 1: Patie
1. Risk of bias		
Describe methods of patient selection:		Describe metho
· Was a consecutive or random sample of patients enrolled?	Yes/No/Unclear	
• Was a case-control design avoided?	Yes/No/Unclear	
• Did the study avoid inappropriate exclusions?	Yes/No/Unclear	
· Could the selection of patients have introduced bias?	RISK: LOW/HIGH/UNCLEAR	
1. Concerns regarding applicability		
Describe included patients (prior testing, presentation, intended use of index test and setting):		Describe includ use of index tes
Is there concern that the included patients do not match the review question?	CONCERN: LOW/HIGH/UNCLEAR	
Domain 2: Index test(s) *(if more than 1 index test was used, please complete for each test)*		Domain 2: Ind *please complete*
1. Risk of bias		
Describe the index test and how it was conducted and interpreted:		Describe the in preted:
• Were the index test results interpreted without knowledge of the results of the reference standard?	Yes/No/Unclear	
• If threshold was used, was it pre-specified?	Yes/No/Unclear	
· Could the conduct or interpretation of the index test have introduced bias?	RISK: LOW/HIGH/UNCLEAR	
1. Concerns regarding applicability		
Is there concern that the index test, its conduct, or interpretation differ from the review question?	CONCERN: LOW/HIGH/UNCLEAR	

Domain 3: Reference standard		Domain 3: Refe
1. Risk of bias		
Describe the reference standard and how it was conducted and interpreted:		Describe the ref interpreted:
• Is the reference standard likely to correctly classify the target condition?	Yes/No/Unclear	
• Were the reference standard results interpreted without knowledge of the results of the index test?	Yes/No/Unclear	
· Could the reference standard, its conduct, or its interpretation have introduced bias?	RISK: LOW/HIGH/UNCLEAR	
1. Concerns regarding applicability		
Is there concern that the target condition as defined by the reference standard does not match the review question?	CONCERN: LOW/HIGH/UNCLEAR	
Domain 4: Flow and timing		Domain 4: Flow
1. Risk of bias		
Describe any patients who did not receive the index test(s) and/or reference standard or who were excluded from the 2x2 table (refer to flow diagram): Describe the time interval and any intervention between index test(s) and reference standard:		Describe any pa or reference star (refer to flow di Describe the tim test(s) and refer
• Was there an appropriate interval between index test(s) and reference standard?	Yes/No/Unclear	
• Did all patients receive a reference standard?	Yes/No/Unclear	
• Did patients receive the same reference standard?	Yes/No/Unclear	
• Were all patients included in the analysis?	Yes/No/Unclear	
· Could the patient flow have introduced bias?	RISK: LOW/HIGH/UNCLEAR	

WHAT'S NEW

Last assessed as up-to-date: 8 November 2016.

Date	Event	Description
30 January 2017	Amended	Protocol amended in response to reviewers' comments

CONTRIBUTIONS OF AUTHORS

Writing first draft of protocol: Elizabeth Boaden; Dawn Doran; Jane Burnell

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Editing protocol: all authors

Agreeing current draft of protocol: all authors

DECLARATIONS OF INTEREST

Elizabeth Boaden: none known

Dawn Doran: none known

Andrew Clegg:none known

Paola Dey: none known

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