

Dysphagia in people with Parkinson's Disease

Protocol

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Introduction

Parkinson's disease (PD) is a neurodegenerative disease which is increasingly prevalent. It is more common with increasing age. The literature suggests that the standardised incidence is 8-18 per 100 000¹. MacDonald et al² in a GP practice survey confirmed this figure finding an incidence of 19 per 100 000 and a life time prevalence of 2 per 1000. More recently, Parkinson's UK estimated the number of cases of PD in the UK to be 145,519, and estimate this to increase and have almost doubled by 2065³.

Dysphagia has been defined as difficulty moving food from the mouth to the stomach⁴. Well-established risk factors for dysphagia include advanced age, neurological disease, head and neck cancer, and pulmonary disease^{5,6}.

Dysphagia is common in PD with early changes to the swallow being subclinical and having no obvious effect. One third of community-dwelling PD patients complain of dysphagic symptoms whilst objectively measured dysphagia rates are much higher, with 4 out of 5 patients being affected^{7,8,9}.

Eating and swallowing problems are distressing to both the patient and carers¹⁰. Drooling, slowness to eat, poor bolus control and preparation as well as fatigue are common. Laryngeal transit takes longer, the swallow may be triggered later and the cough reflex is frequently decreased¹¹. Abnormalities of swallowing, although present, may not be detected until the later stages of the disease or during an acute exacerbation of the disease.

The consequences of dysphagia and aspiration include low-grade pyrexia, chest infection, malnutrition and death^{12,13}. Aspiration pneumonia is a major cause of morbidity and mortality in patients with Parkinson's disease, probably secondary to dyscoordination between breathing and swallowing¹⁴. A meta-analysis on dysphagia and aspiration pneumonia in people who are frail, conducted by Van der Maarl-Weirink¹⁵, confirmed that dysphagia is a significant risk factor for aspiration pneumonia particularly in frail elderly people suffering from cerebrovascular disease.

When people with PD become acutely unwell dysphagia may become evident or worsen. This may be exacerbated by the fact that medication may be withheld or delayed. A Parkinson's UK audit¹⁶ found that 50% of patient's with PD might not get their medication at the correct time. The increased risk of adverse events results in an increased use of health care resources, including medical time in primary care, use of antibiotics and hospitalisation.

Dysphagia is an independent predictor of poor outcome in acute care¹⁷. Nationally there were 324,055 Parkinson's disease admissions in 182,859 patients over 4 years which included 232,905 non-elective admissions. Patients with Parkinson's disease were almost twice as likely to stay in hospital for more than 3 months and even more likely to die in hospital¹⁸.

Speech and language therapy can provide effective dysphagia assessment, management and advice⁷. Dietary modifications and strategies to facilitate swallowing, such as positioning, behaviour modification and chin tuck, have been shown to reduce aspiration risk¹⁹. The identification and management of dysphagia and the resulting prevention of infections has the potential to reduce the impact on the use of healthcare resources. Assessment by speech and language therapists to identify and advise on the management of swallowing problems has the potential to reduce the incidence of community acquired infections and hence hospital admissions. The financial savings would be in the order of £11m as described in 'An economic evaluation of speech and language therapy'²⁰.

Additionally, timely assessment and management of dysphagia can improve the quality-of-life of those with the distressing symptoms as well as family members. The Parkinson's UK audit (2015) showed that only 13% of patient's with PD had access to an integrated multidisciplinary team including speech and language therapists. This highlighted a system level need to address this deficiency.

Guidelines and standards

NICE 2017 Parkinson's Disease in adults NG71

NICE 2011 End of life care for adults (quality standards) QS13

SIGN 2010 Management of patients with stroke – identification and management of dysphagia

National Service Framework 2005 – Long term conditions (quality requirements)

Social care for older people with multiple long-term conditions 2016 (quality standards)

Parkinson's Net 2008 Guidelines for Speech-Language Therapy in Parkinson's Disease

(http://www.parkinsonnet.info/media/14829977/dutch_slp_guidelines-final.pdf)

American Academy of Neurology 2015 Parkinson's Disease Quality Measurement Set Update

(https://www.aan.com/siteassets/home-page/policy-and-guidelines/quality/quality-measures/16pdmeasureset_pg.pdf)

RCP 2016 National Clinical Guideline for Stroke (<https://www.rcplondon.ac.uk/guidelines-policy/stroke-guidelines>)

Parkinson's UK Consensus statement for the optimisation of Parkinson's medicines in hospital <https://www.parkinsons.org.uk/professionals/resources/medicines-optimisation-consensus-statement>

Aims and objectives

Overall aim:

To examine the pathway of care of patients with Parkinson's disease (PD) who are admitted to hospital when unwell. In particular, to identify and explore multidisciplinary care and review organisational factors in the process of identifying, screening, assessing, treating and monitoring the ability to swallow.

Objectives

Organisational

- To examine organisational aspects of clinical dysphagia care including local protocols, and the implementation of national guidelines.
- To review the provision of and access to multidisciplinary care teams.
- To review multidisciplinary training in the hospital environment.
- To review the inter-professional communication particularly within the multidisciplinary care teams.
- To review communication within and between organisations.
- To review the use of care pathways including crossover with primary care and community services.
- To review the availability of out of hours services and the benefit of delivering 7 day working.

Clinical

- To identify and examine remediable factors in a cohort of patients with Parkinson's disease with dysphagia, admitted to hospital.
- To explore the pathway of care from admission to discharge (including death).
- To explore the early identification and management of the difficulty in swallowing (dysphagia) food, drink and medications (both patient/carer and practitioner reported).
- To map access to different facets of care and treatment, triggers to deterioration, multidisciplinary working and discharge arrangements.
- To investigate approaches to long term management, and decision making regarding end of life care including eating and drinking and risk feeding.
- To examine the skill mix of the healthcare professionals involved in the care of this group of patients, throughout assessment, diagnosis and management.
- To identify whether there is a group of patients who fail to receive appropriate care, monitoring and escalation, and to highlight failures in this pathway and risk factors.
- To identify whether there is a group of patients where management of the ability to swallow was not likely to be effective, and where risk feeding and high quality advanced planning and end of life care would be more appropriate.
- To explore adverse events.
- To examine the standards of communication with patients and their carers.
- To review the pharmacological and non-pharmacological management of patients when admitted to hospital and examine the availability of PD medication in acute clinical areas.

Methods

Population/Inclusions

Data will be collected on patients aged 16 and older admitted to hospital with an ICD10 code for Parkinson's Disease over a 8 week period, from Monday 7th January (00:00) – Sunday 3rd March (23:59) 2019. It is anticipated that approximately 80% of patients with PD will also have dysphagia. Including all patients with PD rather than just those with dysphagia will allow us to review those patients who had dysphagia but were not coded, and those patients where dysphagia was not identified/diagnosed.

Patients will be identified using the following ICD10 codes recorded in any position:

- G20 Parkinson's Disease
- G21.1 Other drug-induced secondary parkinsonism
- G21.2 Secondary parkinsonism due to other external agents
- G21.3 Postencephalitic parkinsonism
- G21.4 Vascular parkinsonism
- G21.8 Other secondary parkinsonism
- G21.9 Secondary parkinsonism, unspecified

Data will be collected on patients who are admitted both electively and as an emergency.

Exclusions

The following patients will not be included in this study:

- Patients admitted as a day case
- Patients who are admitted to level 3 critical care
- Patients admitted to independent hospitals

Participating providers of healthcare

All acute hospital providers that admit/treat patients will be asked to participate in the study.

Incidence and prevalence

In 2017/18 the following numbers of hospital admissions of people with Parkinson's Disease were identified via national data (HES, PEDW, ISD and NISRA);

Diagnosis	HES ¹		PEDW ²	NISRA ³	ISD ⁴
	1 ^o	All	1 ^o	1 ^o	1 ^o
R13.X: Dysphagia	48,739	189,736	3,193		
G20.X: Parkinson's disease	12,685	175,354	684	465	444
G21.1: Other drug-induced secondary parkinsonism	246	3,146	27		
G21.2: Secondary parkinsonism due to other external agents	2	37	0		
G21.3: Postencephalitic parkinsonism	6	18	0		
G21.4: Vascular parkinsonism	399	4,856	34		
G21.8: Other secondary parkinsonism	5	96	0		
G21.9: Secondary parkinsonism, unspecified	19	380	0		
J69.0: Pneumonitis due to food and vomit	60,382	118,706	1,766		

¹NHS Digital, Hospital admitted patient care activity 2017-18: Diagnosis

²NHS Wales Informatics Service, PEDW statistics 2017/18

³Hospital Statistics: Acute episode-based activity statistics 2017/18. Includes data on ICD10 codes G20-G26

⁴ISD Scotland National Statistics Publication – November 2017

Method of data collection

There will be two aspects of the study:

1. Information about services available, clinical information and copies of selected case notes will be collected for peer review, to include:
 - Assessment of swallow and the identification of swallowing difficulty
 - Access to specialist staff
 - Medication management in hospital
 - Risk feeding
2. Organisational survey
An organisational questionnaire will be sent to all hospitals and services where patients with dysphagia may be cared for.

Sample Size

Based on population data, over a one year period (2017/18) there were 183,887 patients admitted to hospital with one of the included ICD10 codes in any position; this equates to approximately 15,323 patients a month, (English data only).

Based on the previous research which indicated 80% of patients with PD also have dysphagia, this would indicate approximately 147,109 admissions with dysphagia a year or 12,259 admissions a month.

As part of the scoping exercise, hospitals were asked to indicate how many patients with PD were admitted over a 6 month period, and what the breakdown of elective and emergency admissions was within this. Data from approximately 100 hospitals indicated there were 26,080 admissions over the 6 month period; this is an average of 261 admission per hospital over 6 months or 43 admissions a month. Approximately 32% of admissions were elective and 68% of admissions were an emergency. Over the 6 month period a number of patients were admitted multiple times, and where available approximately 35% of the sample of patients admitted as an emergency were admitted more than once. These data also include patients admitted on a day case basis.

Below are the anticipated sample sizes of each type of data collected:

Data source	Target number
Organisational questionnaire	~300
Clinician questionnaires	~500
Case note review	~500

Sampling cases over an eight week period would enable us to account for multiple admissions, patients admitted as a day case, patients admitted to critical care, and would also enable us to limit the sample to a maximum of two cases per clinician.

Case identification

Within each Trust/Health Board NCEPOD has a Local Reporter (usually employed in clinical audit) who is responsible for providing the details of cases for inclusion to NCEPOD. At the start of the study the Local Reporter will be contacted and sent details of the study criteria. Patients with PD will be identified retrospectively through ICD10 coding via completion of a spreadsheet with selected data from central hospital records. This will include patient details (NHS number, hospital number, age), admission/discharge dates, patient discharge destination (including death)/source of admission, ICD10 codes (primary and all), details of

the admitting consultant, details of any critical care admissions, the details (OPCS codes) of any surgery/procedures undertaken (including PEG insertion).

Once a list of patients has been gathered 500 cases will be sampled for inclusion in the clinical questionnaire and peer review process to ensure hospitals and clinicians are not overburdened.

Study promotion

Prior to data collection, NCEPOD will contact all local reporters and ambassadors and send a study poster to display locally to advertise the study.

Questionnaires

Clinician questionnaire

A clinical questionnaire will be sent to the consultant responsible for the patient at the time of hospital admission. Within this request there will be instruction to pass the questionnaire to most appropriate clinician for completion. The clinical questionnaires will be sent to the NCEPOD Local Reporter for dissemination. Reminders will be sent at six weeks and ten weeks where the data is outstanding. Clinicians will be asked to return copied extracts of the patients case notes to NCEPOD alongside the completed questionnaires (where applicable).

Case note review

Case note review will focus on the group of patients who had an admission during the study period (Monday 7th January (00:00) – Sunday 3rd March (23:59) 2019).

Case notes

Notes relating to the admission will include:

- Clinical notes for the duration of the admission
- Nursing notes
- Advanced Directives or DNAR's
- Referral letters
- Allied Health Professional notes – including speech & language therapy, physiotherapy, occupational therapy, dietetics
- Critical care notes
- Fluid balance
- Weight charts
- MUST charts
- Food charts
- Oral care charts
- Drug charts
- Observations charts
- Mental capacity assessment forms
- Any operation notes/anaesthetic records/consent forms
- Discharge summary

Case notes relating to the 1 year period prior to the index admission:

- Clinic letters

Upon receipt at NCEPOD the case notes will be redacted if not already done so.

Organisational questionnaire

Data collected will include information about the organisation of services, care pathways, the use of guidelines and protocol, and multidisciplinary team working.

Reviewer assessment form

A multidisciplinary group of reviewers (details below) will be recruited to assess the case notes and questionnaires and give their opinions on the quality of care via the reviewer assessment form.

Study method test

The data collection methods and data collection tools will be tested to ensure they are robust.

Analysis and Review of Data

Reviewers

A multidisciplinary group of reviewers will be recruited to assess the case notes and questionnaires and provide their opinion on the care the patients received. The reviewer group will comprise speech & language therapists, care of the elderly physicians, acute care physicians, neurologists, surgeons, laryngologists, physiotherapists, nursing, dietetics, pharmacists, specialist PD nurses/advanced practitioners, occupational therapists and palliative care clinicians.

An advert will be sent to Local Reporters to disseminate throughout the relevant departments. It will also be placed on the NCEPOD website. Successful applicants will be asked to attend a training day where they will each assess the same two cases to ensure consistent assessment. A number of meeting dates will be arranged, and each reviewer will then be asked to attend a further 6 meetings. NCEPOD staff will ensure there is a mix of specialties at each meeting from across the UK. Each meeting will be chaired by an NCEPOD clinical coordinator who will lead discussion around the cases under review. Towards the end of the study the reviewers will be invited to attend a meeting where the data will be presented to and discussed with them. The reviewers will also be sent two copies of the draft report for their comment as this is developed.

Confidentiality and data protection

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will encrypt electronic identifiers and anonymise paper documents. Section 251 approval has been obtained to perform this study without the use of patient consent in England and Wales. Public Benefit Privacy Panel approval has been received for Scotland.

Dissemination

On completion of the study a report will be published and widely disseminated.

Data sharing

Post publication of the study, there is the potential to share anonymised data sets with interested parties working in the same field. This will be undertaken following a strict process and will ensure the data does not become identifiable in their nature due to small numbers.

Timescale

	Dec 18	Jan 19	Feb 19	Mar 19	Apr 19	May 19	June 19	July 19	Aug 19	Sept 19	Oct 19	Nov 19	Dec 19	Jan 20	Feb 20	Mar 20	Apr 20	May 20	June 20	July 20	Aug 20	Sept 20	Oct 20	Nov 20
First meeting of the study advisory group (SAG)																								
Write the protocol																								
Design the questionnaires																								
Write strategy of analysis																								
Advertise the study																								
Design study database																								
Test data collection method																								
Second meeting of the SAG																								
Final protocol to SAG/IAG/HRA																								
Advertise for reviewers																								
Clinical data collection																								
Case reviewer meetings																								
Data analysis																								
Presentation to SAG and Reviewers																								
Presentation to SG																								
CORP IAG																								
Write the report																								
Publish the report																								

References:

1. de Lau LM and Breteler MM. 2006. Epidemiology of Parkinson's disease. *Lancet Neurol*; 5(6): 525-35.
2. MacDonald BK, Cockerell OC et al. 2000. The incidence and lifetime prevalence of neurological disorders in a prospective community-based study in the UK. *Brain*; 123(4): 665-676.
3. Parkinson's UK. 2018. *The Incidence and prevalence of Parkinson's in the UK. Results from the Clinical Practice Research Datalink Summary Report*. Parkinson UK 1/18 (CS2960)
4. Logemann J. 1998. The evaluation and treatment of swallowing disorders. *Current opinion in otolaryngology and head & neck surgery*; 6(6): 395-400.
5. Garon BR, Sierzant T, & Ormiston C. 2009. Silent aspiration: results of 2,000 video fluoroscopic evaluations. *J Neurosci Nurs*; 41(4): 178-85.
6. Smith C, Logemann J et al. 1999. Incidence and patient characteristics associated with silent aspiration in the acute care setting. *Dysphagia*; 14(1): 1-7.
7. Kalf JG, de Swart BJ et al. 2012. Prevalence of oropharyngeal dysphagia in Parkinson's disease: a meta-analysis. *Parkinsonism Relat Disord*; 18(4): 311-5.
8. Takzawa C, Gemmell E et al. 2016. A Systematic Review of the Prevalence of Oropharyngeal Dysphagia in Stroke, Parkinson's Disease, Alzheimer's Disease, Head Injury, and Pneumonia. *Dysphagia*; 31(3): 434-41.
9. Carnerio D, Belo LR et al. 2013. Quality of life in dysphagia in parkinson's disease: a systematic review. *CEFAC. 2013 Set-Out*; 15(5): 1347-1356.
10. Leow LP, Huckabee MA et al. 2010. The impact of dysphagia on quality of life in ageing and Parkinson's disease as measured by the swallowing quality of life (SWAL-QOL) questionnaire. *Dysphagia*; 25(3): 216-220.
11. Ertekin C, Tarlaci S et al. 2002. Electrophysiological evaluation of pharyngeal phase of swallowing in patients with Parkinson's disease. *Mov Disord*; 17(5): 942-49.
12. Schmidt J, Holas M et al. 1994. Videofluoroscopic evidence of aspiration predict pneumonia and death but not dehydration following stroke. *Dysphagia*; 9(1): 7-11.
13. Vanderwee K, Clays E et al. 2010. Malnutrition and associated factors in elderly hospital patients: a Belgian cross-sectional, multi-centre study. *Clin Nutr*; 29(4): 469-476.
14. Gross RD, Atwood CW et al. 2008. The coordination of breathing and swallowing in Parkinson's disease. *Dysphagia*; 23(2): 136-45.
15. Van der Maarl-Weirink CD, Vanobbergen JN et al. 2011. Risk factors for aspiration pneumonia in frail older people: a systematic literature review. *J Am Med Dir Assoc*; 12(5): 344-54.
16. Parkinson's UK. 2015. *2015 UK Parkinson's Audit Summary Report*. Parkinson's UK 05/16 (CS2257)

17. Smithard DG, O'Neill OA et al. 1997. The natural history of dysphagia following a stroke. *Dysphagia*; 12(4): 188-93.
18. Low V, Ben-Shlomo Y et al. 2015. Measuring the burden and mortality of hospitalisation in Parkinson's disease: A cross-sectional analysis of the English Hospital Episodes Statistics database 2009-2013. *Parkinsonism Relat Disord*; 21(5): 449-54.
19. Baijens LW & Speyer R. 2009. Effects of therapy for dysphagia in Parkinson's disease: systematic review. *Dysphagia*; 24(1) :91-102.
20. Marsh K, Bertranou E et al. 2010. *An economic evaluation of speech and language therapy*. Matrix evidence.