



THERAPEUTICS

Development of an integrated care pathway for sialorrhoea

This project has been managed as an independent programme sponsored by Merz Therapeutics UK such that the outputs have been developed by Wilmington Healthcare Ltd, and the expert panel chair and members have been chosen and convened by them. The content is independent of and not influenced by Merz Therapeutics UK who were responsible for checking the final document for technical accuracy only.

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3 | Executive summary

For many patients with Parkinson’s disease, motor neurone disease (MND) and atypical Parkinsonian syndromes such as progressive supranuclear palsy, multiple system atrophy and corticobasal syndrome, management of oral secretions is a major problem.

Unfortunately, clinician awareness about saliva problems, its quality of life impact on patients and the treatment options available, is poor. As a result, patients are typically not proactively asked about sialorrhoea, and many patients are embarrassed to bring it up themselves.

It is essential that all patients experiencing sialorrhoea can access treatment. Sialorrhoea management needs to be incorporated into care pathways for people with Parkinson’s and related conditions to ensure that patients receive the management strategies available, which can be facilitated in a range of settings.

This document has been developed primarily as a resource for Primary Care Networks (PCNs) and Integrated Care Systems (ICSs) when setting up neurology care pathways. Sialorrhoea is not challenging to diagnose but does require healthcare professionals to proactively ask patients about their saliva so that they can access treatment for the problem condition.

Our analysis indicates that hospital admissions for people with sialorrhoea are rising significantly. Many of these are likely to be patients suffering from aspiration pneumonia as a result of sialorrhoea that has not been adequately addressed. No doubt many more patients are admitted who do not have a diagnosis of sialorrhoea formally recorded.

Sialorrhoea needs to be identified early so that patients can access the interventions that have life-changing consequences, as left untreated, sialorrhoea often has a detrimental impact on quality of life. Therefore, a systematic approach to identifying those at risk of sialorrhoea is needed.

This integrated care pathway resource has been created in a collaborative effort by a team of experts to support the detection and care of patients with sialorrhoea. We hope it will be a useful resource locally for both healthcare professionals and commissioners, to map the patient journey and ensure best practice care.

4 | About sialorrhoea

Secretion problems relate either to thin, watery saliva or thick, tenacious saliva, mucus, and phlegm. For people with thin saliva, they may experience pooling of large amounts of thin watery saliva, which can cause drooling. Although a normal amount of saliva is produced by those with Parkinson’s, around two to three pints every day, excessive saliva is a commonly reported symptom. In most cases, saliva problems are the result of increasing weakness of muscles in the mouth, tongue and throat and reduced frequency of reflexive swallowing. This can make it difficult to manage saliva, both in the mouth and during swallowing. Drooling is worse if the person has a poor lip seal or swallowing difficulties (dysphagia).

People with thick saliva may experience thickened mucus in the mouth and throat, which is difficult to swallow. Additionally, phlegm in the airways may be difficult to cough up due to weakened respiratory muscles and poor cough. Thick mucus can build up in the mouth and at the back of the throat due to dehydration, mouth breathing or open mouth posture, which can lead to evaporation of saliva.

Many patients with sialorrhoea go undiagnosed, and as such develop issues like aspiration pneumonia that can lead to hospitalisation. The data over the last 5 years shows a year on year increase in the number of inpatient spells where sialorrhoea has been coded, see figure 1. Figure 2, shows the number of inpatient spells for sialorrhoea, who also have a diagnosis for MND or Parkinson’s (see the data analysis methodology in section 11). More broadly, figures 3, 4 and 5 show the non-elective admissions burden of aspiration pneumonia, pneumonitis and respiratory infection respectively for patients with Parkinson’s or MND. While these diagnoses have a number of causes and are certainly not all attributable to sialorrhoea, especially since these are complex patients with multiple problems, sialorrhoea will in many cases be a factor affecting these patients’ health. Unfortunately, since sialorrhoea is underdiagnosed and therefore not recorded, it is difficult to know the extent to which it plays a role in these admissions and the associated costs however it does place additional demand on services.

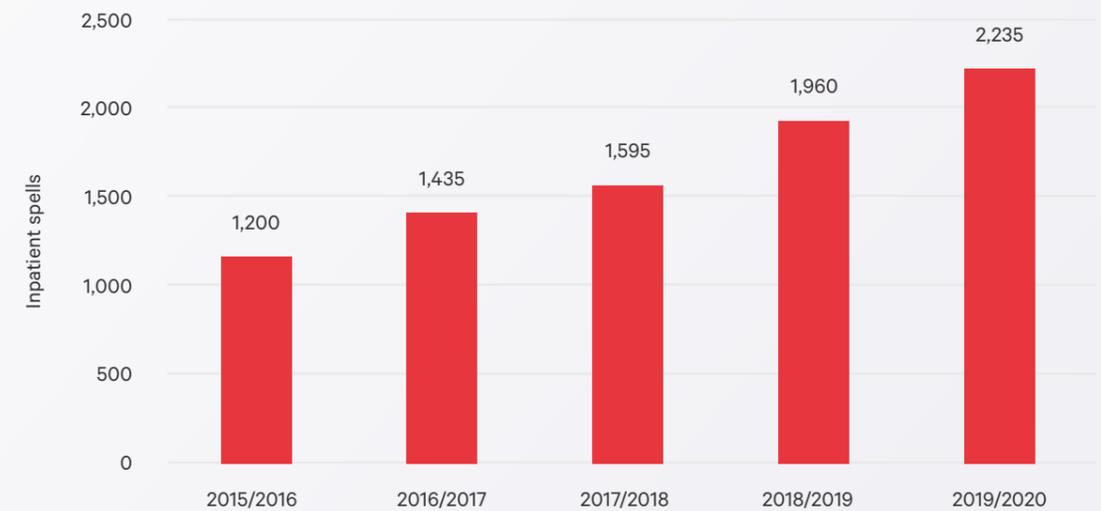


Figure 1. Sialorrhoea inpatient spells¹

4 | About sialorrhoea

Figure 2: Sialorrhoea inpatient spells by condition¹

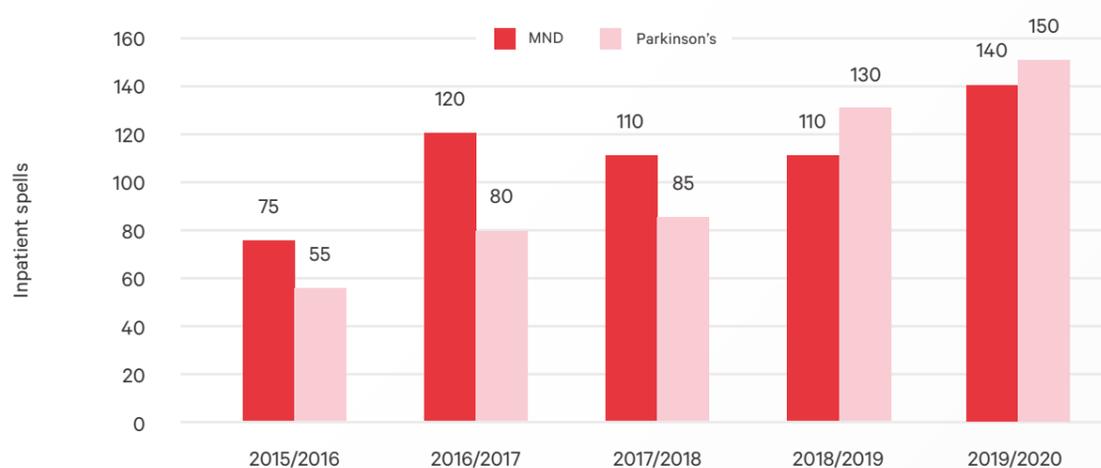


Figure 3: Non-elective admissions for aspiration pneumonia (J69 'Pneumonitis due to solids and liquids') with either Parkinson's or MND¹

Year	Spells	Patients	Cost
2015/2016	3,995	3,475	£19,113,483
2016/2017	4,835	4,230	£22,528,043
2017/2018	5,615	4,860	£30,548,824
2018/2019	5,820	5,000	£32,778,340
2019/2020	6,335	5,360	£40,161,812

Figure 4. Non-elective admissions for pneumonitis with Parkinson's disease or MND in 2019/20¹

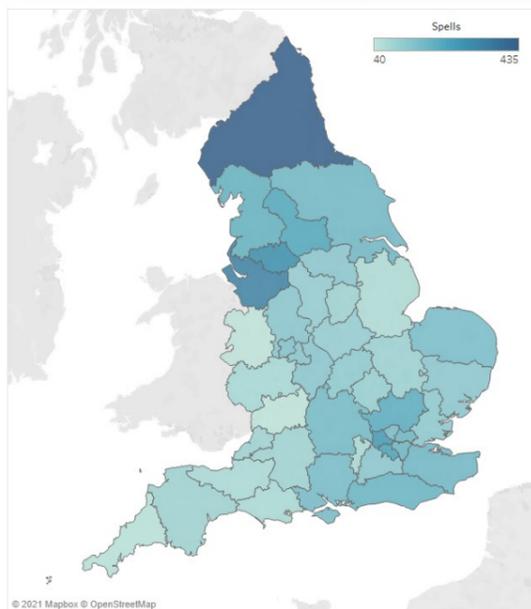
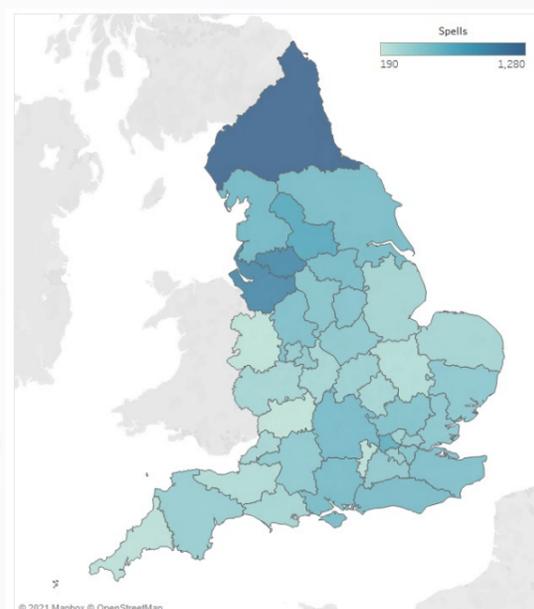


Figure 5. Non-elective admissions for respiratory infection with Parkinson's disease or MND in 2019/20¹



5 | Developing the integrated care pathway

The aim of this integrated pathway is to improve the identification of sialorrhoea and ensure timely referral into specialist care.

The clinical advisory group was set up in order to produce a template for sialorrhoea management, in order to support local areas in identifying patients sooner, with clear advice of what should be done, over what timescale and to whom patients should be referred for specialist care.

The pathway also gives advice on information for patients who may not realise that their condition warrants intervention. Patients need to be empowered to help ensure that drooling issues are brought to the attention of healthcare professionals (HCPs).

The objectives of the sialorrhoea pathway are to:

- Improve early detection rates of sialorrhoea
- Initiate timely referral and treatment for people with sialorrhoea
- Identify those needing urgent referral within 2 weeks
- Ensure equity of access to specialist assessment, diagnosis and treatment
- Reduce morbidity to sialorrhoea, including reducing hospitalisation
- Give patients access to education about their condition

5.1 | Covid-19

The COVID-19 pandemic has had a significant impact on services. Closure of clinics, social distancing requirements and staff redeployment has reduced capacity. The number of hospital referrals and follow-up appointments being carried out has fallen. This creates a large backlog of patients that need to be seen in secondary care and also increases the projected number of patients in the community who require investigation and potential onward referral.

Key principles of service delivery include:

1. Integration

Services should be delivered on the basis of networks or systems of care that are fully and seamlessly integrated from community to tertiary care.

2. Utilise technology

Systems of care should be designed with a patient-centric approach with an emphasis on the use of technology to facilitate diagnostics, monitoring and communication at all levels.

3. Standardisation

Primary/community care management of neurology patients at risk of sialorrhoea should be standardised and improved.

5.2 | Methodology

This integrated sialorrhoea care pathway was developed using a Delphi-style consensus process involving experts in this field.

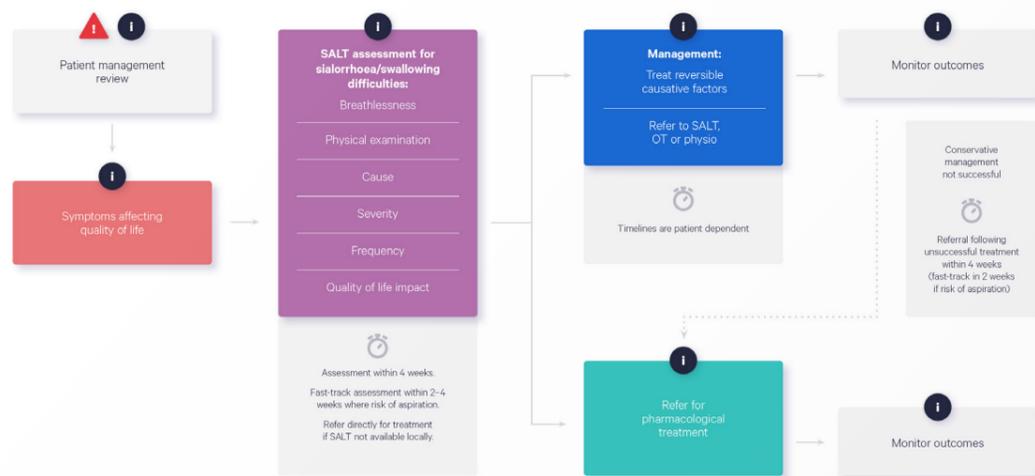
6 | Mapping the pathway

Better awareness of sialorrhoea, among both patients and HCPs, will ensure that more patients are directed onto the care pathway and therefore more patients would be able to access timely treatment. A proactive management

approach is vital to increase diagnosis and management of patients affected by the condition.

The overall pathway for sialorrhoea maps the patient journey from presentation to diagnosis, referral, intervention and ongoing management (see Figure 6).

Figure 6.
The
sialorrhoea
care pathway



The pathway gives ideal timelines for assessment:

- Assessment within two to four weeks.
- Rapid two-week assessment for patients at risk of aspiration.

Further information and alerts provide more detail on important topics which are detailed in the sections below.

6.1 | Audit points, key performance indicators and standards for care

Services need to be benchmarked regularly to monitor local variation, to track improvement efforts and to highlight areas that need attention. Services should be audited against the timelines set out within the pathway and against local population with conditions known to put them at-risk for sialorrhoea.

Existing guidelines provide an important standard on which sialorrhoea can be modelled: for Parkinson's disease (NICE Guideline NG71²) and MND (NICE Guideline NG42³).

There are also publications relating to botulinum toxin A (NICE TA605⁴) and resource impact report⁵, and oral glycopyrronium bromide (evidence summary⁶).

The care pathway provides a set of audit points and key performance indicators to enable services to quantify performance and gauge progress on a regular basis:

Audit points:

- Number of people asked about sialorrhoea
- Number of people with sialorrhoea offered treatment (non-pharmacological or pharmacological)
- Documentation of review at next appointment
- Number of people seen by SALT within 4 weeks of referral
- Number of people seen by clinician for treatment within 2 to 4 weeks of referral

Key performance indicators:

- Proportion of people seen who have been asked about sialorrhoea
- Proportion of people with sialorrhoea offered treatment (non-pharmacological or pharmacological)

6.2 | Professional awareness of sialorrhoea

Sialorrhoea is an under recognised problem in patients with conditions like Parkinson's and MND, where drooling may be a very early symptom. It is important to treat sialorrhoea as early as possible before the problem worsens and/or complications such as chest infections arise. Treating sialorrhoea can have a huge impact on improving a patient's quality of life and must not be underestimated. By also improving detection rates it will enable more patients to be referred onto the care pathway to access the appropriate treatment.

While sialorrhoea severity may be low, the impact on patients can be large. HCP awareness of the issue, its overall quality of life impact, related problems like aspiration and respiratory infection, and of new effective treatment developments, is poor. As a result, proactive engagement and referral from GPs is poor, and secondary care is not seeing sialorrhoea as a priority.

It is important for HCPs to:

- Understand the symptoms of sialorrhoea
- Differentiate between thick or thin secretions
- Be aware of the treatment pathway
- Understand the risk of cognitive problems in patients treated with antimuscarinic and anticholinergic therapies

Sialorrhoea management should be incorporated into the care pathways for Parkinson's and other conditions to ensure patients have access to treatment.

6.3 | Communication with patients

It is important that HCPs are communicating with patients about sialorrhoea and proactively asking them about this. Parkinson's nurse specialist review (e.g. NMS checklist or UPDRS) may highlight sialorrhoea and trigger referral. Many patients find drooling embarrassing and avoid bringing it up. Discuss sialorrhoea with the right questions in the right way. Ask about:

- Wet pillows, pyjamas etc.
- Dry mouth.
- Nasal drip.
- Choking, pooling.
- Thick saliva (may put people off food, leading to weight loss).
- Impact on carers.
- Impact on food sensation.
- Daily living impact (NB. often worse than Parkinson's!)
- Time of day/night, severity, sore mouth?
- Increases chances of falls, as preoccupied with drooling.
- Aspiration pneumonia.
- Checklists / rating scales

Patients should be reviewed regularly to monitor outcomes (assessment every 1-3 months). Video/phone consultations are helpful for many patients where travel is difficult. It is essential that patients have a clear contact point should issues arise and that GPs have a direct contact for clinical questions.

6 | Mapping the pathway

6.4 | Patient information

Saliva problems can have a profound impact on patients, causing embarrassment and issues with speech and swallowing. However, most patients are not aware that there are a number of behavioural and exercise strategies that can help manage drooling issues and also medications that help reduce saliva production.

Patients and carers are often not aware that drooling problems (sialorrhoea) are related to their condition or that these issues can be managed, and therefore do not bring them up with healthcare professionals. Many people don't ask for help because they are too embarrassed to discuss it or they think it's something they should just have to put up with. It is important that patients are made aware of sialorrhoea and who to talk to should they experience these problems.

Problems linked with saliva that is either too watery or too thick can have an impact on: embarrassment (oral hygiene, odour, appearance, eating out), dryness, speech clarity, swallowing and aspiration (breathing in saliva or food).

This can be brought about by Parkinson's medication, cognitive difficulties, weakness of muscles in the mouth and tongue which have been brought about by Parkinson's.

There are a number of behavioural strategies for managing drooling issues which are focused on body positioning and behaviours and exercises that promote regular swallowing and reduced drooling. There are also medications that help reduce drooling problems, including injections into the salivary glands that help reduce saliva production.

6.5 | Assessment

Assessment should be performed by SALT and should be fast-tracked if the patient is at risk of aspiration. Assess the patient to understand their sialorrhoea: this should include physical examination, causes of sialorrhoea, body posture including head and neck control, severity and frequency, and quality of life impact.

It is important to note that SALT provision around the country varies. Where SALT assessment is not available, patients should be directly referred for treatment.

Physical examination

It is important to carry out full formal examination of the mouth, lips and chin, checking for sores, cracks and skin lesions etc, as well as body posture (especially head and neck control) and respiratory function (for example in patients with MND). Diagnostic criteria: anterior vs posterior drooling.

Record symptoms on scale (DSFS) Patient outcome measurement tool

Drooling severity score:		Drooling frequency score:	
Dry Never drools	1	Never	1
Mild Wet lips only	2	Occasionally	2
Moderate Wet lips and chin	3	Frequently	3
Severe Clothing becomes damp	4	Constantly	4
Profuse Clothing, hands, objects become wet	5		

Causes of sialorrhoea

Oral health must be assessed holistically to understand causative factors related to the primary condition (e.g. current control of Parkinson's) and other associated factors, such as reflux, posture, polypharmacy (e.g. medication induced drowsiness or poor swallowing) or denture issues (poor closure of the mouth) that need to be addressed.

Assessment tools

The Parkinson's Disease Questionnaire (PDQ-39)

Non-motor symptoms questionnaire

ROMP saliva questionnaire⁸

Example Drooling in Parkinson's Assessment

Body posture including head and neck control

Review Parkinson's medication to control any dystonia or rigidity that affects body positioning and leads to drooling. Review patients with other conditions, for example to address focal dystonia/hyperextension of the neck in people with progressive supranuclear palsy (PSP) hypertonia (may benefit from botulinum toxin to improve head position).

Severity and frequency

Assess the severity and frequency of drooling using the Drooling Severity and Frequency Scale (DSFS). This can also help with identifying the patient's treatment goals.

Quality of life impact

It is essential to assess the impact of drooling (and its aftereffects) on quality of life, as often this can be worse than the patient's primary condition. Patients should complete a self-assessment (e.g., ROMP saliva questionnaire⁸) to get a baseline measure and monitor their progress throughout treatment (a Parkinson's nurse specialist may assist with this).

6.6 | Management

There are a number of management strategies to help treat the factors involved in drooling, such as positioning and behaviours and exercises that promote regular swallowing and reduced drooling, which can be supported with referrals to SALT, occupational therapy and physiotherapy.

Patients with cognitive difficulties or difficulty forming new habits may however struggle. Those for whom conservative management approaches are not effective, or where SALT services are not available, should be referred for pharmacological treatment.

Medicines management	Positioning	Sensory stimulation, oromotor exercises	Diet & hydration	Behavioural programme
<ul style="list-style-type: none"> Review of all current medicines, especially any treatments for sialorrhoea. 	<ul style="list-style-type: none"> Encourage small changes in positioning, such as: <ul style="list-style-type: none"> Head position. Seating position. Eating position. Sleeping position. Positioning during daily tasks to reduce the loss of saliva from the mouth. Equipment to support posture/positioning. 	<ul style="list-style-type: none"> Simple techniques to increase oral stimulation and promote regular swallowing: <ul style="list-style-type: none"> Sips of ice, fizzy or citrus-flavoured fluids. Use of sugar-free chewing gum, boiled sweets to stimulate swallowing/reduce viscosity of saliva. Cold temperatures to stimulate swallowing. Exercises aimed at improving oral function. Cough management techniques, which may help to clear thick, tenacious saliva. Suctioning. 	<ul style="list-style-type: none"> Rehydration. Increase the intake of fluid, for example with jelly, frozen mousses or ice lollies. Drinking pineapple or papaya juice before/with a meal. These juices contain proteolytic enzymes, bromelain (pineapple – most concentrated in the core) and papain (papaya), which help break down protein in mucus. The juices can also be applied gently on a sponge as part of a mouth care regimen. Reducing intake of dairy products may be helpful. Check with the dietitian, as some people with limited diets due to dysphagia may rely on dairy products to maintain their weight. 	<ul style="list-style-type: none"> A programme designed to remove or introduce behaviours for the purpose of reducing drooling: <ul style="list-style-type: none"> Regular swallows. Swallowing technique. Regular sips of fluid. Intensive swallow prompt programme. Lip closure. Exercises to improve weakness in oral and facial muscles or tongue. Regular dabbing of chin. Avoidance of mouth breathing, if possible.

Figure 7.
Management strategies

6 | Mapping the pathway

6.7 | Treatment

- Where conservative management measures are not successful, people with Parkinson's and atypical Parkinsonian syndromes may be referred for pharmacological treatment.

Figure 8. Sialorrhoea treatment pathway for Parkinson's (NICE)



NICE guidelines for Parkinson's recommend:

- Glycopyrronium bromide (not currently licenced for sialorrhoea in adults).
- XEOMIN® (botulinum toxin A) (licenced for sialorrhoea).
- Only consider anticholinergic medicines other than glycopyrronium bromide (e.g. topical atropine around salivary glands, hyoscine patch - not currently licensed for sialorrhoea in adults) if risk of cognitive adverse effects is thought to be minimal.

NICE guidelines for sialorrhoea in MND recommend:

- First-line trial anti-muscarinic medication.
- For people with cognitive impairment, first-line consider glycopyrronium bromide.
- Second-line refer for XEOMIN® (botulinum toxin A).
- (For thick, tencious saliva consider treatment with humidification, nebulisers and carbocisteine).

NB. Potential adverse events will be different for patients with MND, Parkinson's and other atypical Parkinsonian syndromes.

Dryness (xerostomia) is a risk factor in all pharmacological treatment, especially risk to dentition, oral hygiene, swallowing and digestion. Consider ways of managing dryness, e.g. artificial saliva, increased oral/dental hygiene regimes etc. Before starting any drying agent, the risks and how to manage this should be discussed with the patient.

Dosing:

Glycopyrronium bromide

- Titrate slowly to a maximum dose of 1.5 mg per dose three times a day. NICE suggest 1.5–3 mg per dose max TDS⁵.

XEOMIN® (botulinum toxin A)

- Refer to: movement disorders specialist, neurologist, care of the elderly, rehabilitationist or specialist nurse.
- Assessment for: cognitive impairment, suitability for treatment (ability to behaviourally manage secretions reducing saliva).
- Identify where injection services are provided. These may be undertaken in a range of locations (does not have to be specialist centre): neurology department, rehab services, community, including delivery at home.
- No more frequent than 16 weeks, for follow up.
- Medication considerations: confusion, dryness, effects on swallowing of injection, costs, who manages this?

Topical atropine

- Atropine eye drops 1% 1–2 drops on a cotton bud around the salivary glands 4 times a day.

Hyoscine patch

- Hyoscine hydrobromide patch is a set dose of 1.5 mg.

7 | Costing

Delivering pharmacological treatment with botulinum toxin A for patients with sialorrhoea could be performed in either a community or outpatient setting, although the latter would be more costly. A community clinic delivery model in which nurses administer injections is the most cost-effective approach. To give an idea of the delivery cost involved, a band 5 nurse serving patients directly costs £63 per hour (£89 for band 6). Assuming a nurse

could treat three patients an hour, the average patient cost per treatment would be £21 to £30 depending on nurse banding. Note that the scale of the service would need be large enough that the nurse is either fully occupied or can work on other services for these efficient unit costs to apply. Costs associated with consumables and cleaning would also need to be added.

8 | Conclusion

Improved diagnosis and referral offers an opportunity to make a substantial difference to patients with sialorrhoea. Patients need early identification and intervention; however, many people are too embarrassed to raise the issue with their HCPs and HCPs are not always asking their patients

about drooling, which can have a major impact on quality of life. There needs to be increased awareness among HCPs about the importance of asking about sialorrhoea in order to direct people onto the care pathway towards the treatment they need.

9 | Resources

- NICE (2017) NICE Guideline NG71. Parkinson's disease in adults
- NICE (2016) NICE Guideline NG42. Motor neurone disease: assessment and management
- NICE (2019) Technology Appraisal Guidance TA605. XEOMIN® (botulinum neurotoxin type A) for treating chronic sialorrhoea
- NICE (2019) Resource impact report: XEOMIN® (botulinum neurotoxin type A) for treating chronic sialorrhoea (TA605)
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10 | Glossary of abbreviations

DSFS	Drooling Severity and Frequency Scale
HCP	Healthcare professional
HES	Hospital Episode Statistics
ICS	Integrated care system
MND	Motor neurone disease
NMS	Non-motor symptoms
OT	Occupational therapy
PCN	Primary care network
PSP	Progressive supranuclear palsy
ROMP	Radboud Oral Motor Inventory for Parkinson's disease
SALT	Speech and language therapy
TDS	Three times a day
UPDRS	Unified Parkinson's Disease Rating Scale

11 | Data analysis methodology

Summary	Tabulation of HES data for admissions in patients with drooling-related diagnoses
Source	Hospital Episode Statistics (HES)
Fiscal years	2015/2016 to 2019/2020
ICD-10 Codes	<p>Parkinson's F023 - Dementia in Parkinson disease G20X - Parkinson's disease</p> <p>MND G122 - Motor neuron disease</p> <p>Diseases of salivary glands K11 - Diseases of salivary glands K117 - Sialorrhoea</p> <p>Pneumonitis J69 - Pneumonitis due to solids and liquids <i>Aspiration pneumonia (due to): food (regurgitated) / gastric secretions / milk / vomit / not otherwise specified</i></p> <p>Respiratory infection J00-J06 - Acute upper respiratory infections J09-J18 - Influenza and pneumonia J20-J22 - Other acute lower respiratory infections</p>
Metrics/Suppression	<p>Spells, Appointments, Patients: Values above 7 have been rounded to the nearest 5; due to this totals may not sum across columns/rows. Values between 1 and 7 inclusive have been suppressed and are represented by *. Cost has been rounded to the nearest pound.</p>

12 | References

¹Secondary care data is taken from the English Hospital Episode Statistics (HES) database produced by NHS Digital. Copyright © 2021, NHS Digital. Re-used with the permission of NHS Digital. All rights reserved.

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