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#### Approval process

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1. Introduction

Drooling is a significant issue for a small proportion of the paediatric population.

Improving chronic drooling can help with patient hygiene, reduce secondary infections caused by constant wet and macerated skin and improve patient quality of life and self-esteem.

NICE published a guideline on the management of cerebral palsy in the under 25s (Jan 17) and an evidence summary on the treatment of chronic drooling (Feb 17). These have been incorporated into this guideline.

2. Purpose

This guidance covers the management of drooling in children.

3. Definitions / Abbreviations

Sialorrhoea - chronic pathological drooling
Acetylcholine - ACh

4. Duties

4.1 Chief executive
Should ensure that all clinical staff working with children and young people have access to this guideline. Should ensure that appropriate training and updates are provided to all relevant staff groups. Should ensure that staff have access to appropriate equipment that complies with safety and maintenance requirements.

4.2 Managers
Managers should ensure that staff are aware of and have access to policy guidelines. Staff training needs should be highlighted and addressed. Appropriate education, supervision and mechanisms are in place to ensure good practice.

4.3 All clinicians working with children and young people
To be aware of the guideline and follow appropriately.

5. Drooling

Drooling (or dribbling), where saliva is present beyond the lip margin and is normal in babies and infants. As neurological control of the tongue and bulbar musculature develops, salivary “continence” normally occurs by 15–18 months, though a high number of typically developing children will continue to drool up until the age of 3 years, especially during eating and drinking. The ability to control saliva develops alongside normal feeding and oral-motor control.

It is certainly considered abnormal to have problems with saliva control (drooling) beyond the age of 4 years.

The unconscious swallowing of saliva is a complex process and is indeed one of the most intricate motor functions in a human. The coordination of over 25 pairs of bulbar muscles is vital to maintain the integrity of the swallow reflex.
5.1 Prevalence of Drooling in Children
The overall prevalence of significant chronic drooling in childhood is put at up to 0.6%. The commonest population group with severe and persisting difficulty is children with quadriplegic cerebral palsy where the prevalence rate is as high as 30–53%.

5.2 Consequences of Drooling
The consequences of poor saliva control include negative comments from other children, unpleasant odours, social embarrassment and isolation and specific physical problems such as dehydration and skin breakdown.

5.3 Saliva Production
A child will typically produce 1–1.5 litres of saliva every day. There is little information available on the frequency of swallowing in children, but adults swallow approximately once every minute while awake. Although this is an automatic act, it is also dependent on the ability to feel the build-up of saliva within the mouth as well as normal movement of the tongue to collect it and transfer it to the back of the mouth for swallowing.

Saliva production occurs predominantly in three pairs of salivary glands, the submandibular, sublingual and parotid. The submandibular glands produce the watery saliva that bathes the oral cavity at rest, approximately 65–70% of total production. The sublingual glands produce a small amount of thicker saliva that tends to coat the teeth and the parotid glands produce about 20% of the total, comprising watery secretions that are important for chewing and swallowing.

Neurologically, the salivary glands are under the automatic control of the parasympathetic (secretory excitation) as well as the sympathetic (alters viscosity) nervous system. These in turn are regulated by external somatic stimuli such as vision, smell and taste. The parasympathetic fibres originate in the pons and medulla of the mid-brain and synapse in the otic (parotid) and submandibular (submandibular and sublingual) ganglia. The postganglionic parasympathetic fibres release ACh at the nerve endings; this neurotransmitter directly stimulates the secretion of saliva in the relevant gland.

Saliva is important for maintenance of a homeostatic microenvironment in the mouth, at rest and at times of feeding; keeping the acid–base and bacterial balance optimal, having bacteriostatic and bactericidal effects. Lubrication of the oral cavity is vital to maintain dental and oral hygiene and to facilitate ease of swallowing. It is also important for the early stages of carbohydrate digestion.

5.4 Aetiology
Drooling may result from the hypersecretion of saliva or, more commonly, impairment of swallowing.

Developmental causes: A mild degree of drooling is normal during infancy. The problem seems to be more prominent around five to six months of age when salivation increases to its full capacity. Drooling occurs because of the infant’s limited ability to swallow, the lack of front teeth to serve as a dam and the adaptation of the infant’s mouth in the opening position. Drooling normally disappears by two years of age as a consequence of physiological maturity of oral motor function.
Physiological causes: Drooling is a common sign of teething. The salivary reflex is stimulated by eruptions of teeth with resulting hypersecretion of saliva. Hypersecretion of saliva occurs with nausea. The salivary nuclei are excited by both taste and tactile stimuli from the tongue and other areas of the mouth. Ingestion of certain foods, particularly sour or spicy ones, may increase salivary flow. Salivation can also be stimulated by impulses arriving in the salivatory nuclei from higher centres of the brain. As such, marked salivation may occur when a person smells or eats his or her favourite foods. Hypersecretion of saliva may also occur with pleasurable sensation or anticipated pain, presumably through activation of higher centres.

Central nervous system and muscular disorders: Drooling is a common occurrence in children with central nervous system and muscular disorders, such as cerebral palsy, facial nerve palsy and myasthenia gravis. A significant number of these patients have dysfunction in the oral and pharyngeal phases of swallowing, insufficient sensory appreciation of external salivary loss, or a structural or functional inability to close the lips during the oral phase of swallowing. Dysfunction in the oral and pharyngeal phases of swallowing may be secondary to uncoordinated tongue movements, high tonus and spastic contraction of the pharyngoesophageal sphincter, dyscoordination between the pharynx and sphincter, and a lack of coordinated control of head and neck musculature.

Learning Disabilities: Drooling occurs in approximately 10% of children with learning disabilities. Drooling may be secondary to a delay in the development of coordinated swallowing movement, inefficient and infrequent swallowing, lack of awareness of oral incompetence, and incomplete lip closure during swallowing. Many children who drool have an infantile tongue thrust, which may cause problems with eating and swallowing.

Oropharyngeal lesions: Acute infections involving the mouth or throat such as gingivostomatitis from herpes simplex virus or coxsackie virus may cause hypersecretion of saliva. Other oropharyngeal lesions may cause drooling because of pain or abscess, epiglottitis and damage to the oral or pharyngeal mucosa from caustic ingestion or direct trauma.

Oesophageal lesions: Drooling may result from oesophageal obstruction such as may occur with oesophageal stricture or a foreign body in the oesophagus. Drooling may also result from the ingestion of caustics or corrosive acids with injury to the oesophagus.

Gastroesophageal reflux: Episodic hypersalivation and drooling may result from gastroesophageal reflux. It is believed that stimulation of the oesophagus by gastric acids excites an oesophagosalivary reflex.

Drugs and chemicals: Drugs that may cause drooling include morphine, pilocarpine, methacholine, haloperidol and clozapine. Drooling secondary to the use of benzodiazepines such as nitrazepam can be explained by drug-induced cricopharyngeal incoordination with impaired swallowing. Drooling is a prominent feature of poisoning with mercury, selenium and organophosphate compounds. Drooling may also result from cocaine or phencyclidine intoxication. In the neonatal period, drooling may be a sign of withdrawal from maternal substance abuse.
6. CLINICAL EVALUATION.

6.1 History
It is important to take a thorough history, focusing especially on oral-motor control and aspects that may increase the problems of drooling such as posture, medication, dental health, ENT symptoms and neurological status. Gastrointestinal reflux and constipation, the frequency of urinary flow and chest health are also of relevance.

Age of onset: Drooling in the neonatal period should alert to the possibility of oesophageal atresia or withdrawal from maternal substance abuse. A mild degree of drooling is normal during infancy.

Chronicity: An acute onset suggests an infection or drug intoxication. Drooling of long duration may be developmental or secondary to a structural lesion, neuromuscular disorder or learning disability.

Severity: Severe drooling can lead to social embarrassment. The severity can be gauged by the frequency of bathing, wiping and need for bibs or clothing changes.

Precipitating factors: Any precipitating factors such as ingestion of food and teething should be noted.

Associated symptoms: Fever, agitation, aphonia, dyspnoea and stridor suggest epiglottitis. Fever, sore throat and dysphagia suggest peritonsillar abscess. A history of choking, gagging, coughing, vomiting and dyspnoea suggests a foreign body in the oesophagus. A history of regurgitations, especially since the neonatal period, is suggestive of gastroesophageal reflux. Lacrimation, sweating, headache, dizziness and cramps suggest intoxication with organophosphates. Feeding difficulties, excessive sweating, syncope, insensitivity to pain, slurred speech and seizures are features of familial dysautonomia.

Developmental history: A thorough developmental history is important.

Drug use: A detailed drug history is important.

Psychosocial history: Any psychosocial or emotional stress should be noted as a potential cause of the drooling as well as the impact of drooling on the child and family.

Perinatal history: The perinatal history should include maternal illness during the pregnancy, gestational age at birth, birth weight, perinatal trauma, asphyxia and infections.

Past history: Significant illnesses such as cerebral palsy, facial nerve palsy, myasthenia gravis and gastroesophageal reflux should be noted.

Family history: A family history of Wilson disease, Rett syndrome or familial dysautonomia suggests the corresponding disorder.
6.2 Examination
A clinical examination focusing on the dental health, postural control and the neurology of the tongue, cranial nerves, bulbar region, swallowing and the respiratory system.

**General:** Weight, height and head circumference should be plotted on standard growth charts.

**Associated signs:** Dysmorphic features may suggest certain syndromes. Fever, trismus, a swollen and inflamed tonsillar area, and deviation of the uvula to the opposite side suggest peritonsillar abscess. Toxicity, fever, respiratory distress with inspiratory stridor, flaring of the alae nasi and inspiratory retractions of the suprasternal notch suggest epiglottitis. Spasticity, hyperreflexia, ankle clonus, extensor plantar response, dysarthria, athetosis, ataxia and contractures suggest cerebral palsy.

6.3 Quantification
Quantification of the problem focuses on how disruptive the drooling is on general activities of daily living and quality of life. There are a number of scales used:

1. The **Drooling Rating Scale** - Thomas-Stonell and Greenberg classification is useful for evaluating drooling severity and frequency.

2. The **Drooling Impact Scale** (DIS) is an evaluative tool to assess the effect of saliva-control interventions on drooling in children with developmental disabilities.

3. The **modified Teacher's Drooling Scale** (mTDS) is a 9-point scoring system measured by parents/carers.

4. A “**bibometer**” or “**bib diary**” of how many bibs are necessary during the course of a day is useful as a rough measure of drooling.
7.0 Management

Management of drooling can be broken down into four areas, which are not necessarily mutually exclusive.
1. Conservative/alternative
2. Specific oral-motor exercises
3. Medical
4. Surgical interventions

A specific, individualised management plan is then drawn up with the child and family. Many different aspects of salivary control may be focussed on. The overall guiding philosophy is to optimise the quality of life of the child, without compromising oral health. Significant improvements in self-esteem and social interaction can be gained by successful management programs.

7.1. Conservative/alternative

If dental problems, such as malocclusion, gum disease or caries, are present these should be dealt with specifically. Routine good oral health is vital, especially if considering treatment options that may reduce the amount of saliva secreted into the mouth. If problems with the adenoids or tonsils causing nasal obstruction are discovered, referral to ENT may be indicated. Postural control of the head, neck and trunk may also need to be addressed.

If a child is able to wipe his/her own mouth, the use of sports towelling wristbands may be more socially acceptable, particularly to peers, than handkerchiefs or bibs as the child gets older. “Dabbing” rather than “wiping” across the mouth and chin causes less local stimulation to the saliva glands.

Prevention of excessive mouthing of fingers or objects helps reduce the stimulus of saliva production and encourages lip closure. Simple distraction therapy is generally best for this.

Sweet fizzy drinks can cause direct effects on increasing saliva production, as can very acidic food stuffs such as vinegar or lemon juice. It is, therefore, best to avoid them.

7.2. Oral-motor exercises

If an individual child has appropriate levels of attention and compliance, specific oral-motor exercises can be helpful. Some children, if they are able to follow directions, can achieve control of their saliva with the help of tongue and mouth exercises organised by speech and language therapists. It often takes a considerable period of time to improve the situation, and the control gained is often very dependent on the level of concentration of the child and what other tasks are being performed at the same time.

The family and carers must “buy in” to oralmotor programs too as the child will need considerable long-term encouragement and support in order to gain any degree of success. The evidence base for oral-motor therapy is very limited, particularly in children with severe disabilities, and clinical experience suggests this approach is only applicable to children with mild to moderate oral dysfunction, good cognitive skills and a high level of motivation.
7.3. Medical

To reduce the severity and frequency of drooling consider the use of anticholinergic medication. The secretion of saliva is under parasympathetic autonomic control, with ACh working as the specific neurotransmitter, downregulation of ACh would theoretically lead to a reduction in the production of saliva.

- Glycopyrronium bromide (oral or by enteral tube) or
- Transdermal hyoscine hydrobromide or
- Trihexyphenidyl hydrochloride for children with dyskinetic cerebral palsy, but only with input from specialist services.

When choosing which medicine to use, take into account the preferences of the child or young person and their parents or carers, and the age range and indication covered by the marketing authorisations.

Regularly review the effectiveness, tolerability and side effects of all drug treatments used for saliva control.

**Hyoscine patches—topical**

Transdermal hyoscine patches (scopolamine, Scopoderm TTS, Novartis Consumer Health) have been used in the management of drooling for a long period. It is not licensed for the treatment of drooling. There is considerable variation in efficacy between individuals; many find them extremely useful, especially for short term use.

However, allergic skin reactions at the site of use are frequent and troublesome, and problems with deterioration in seizure control have been reported. Xerostomia (uncomfortable dry mouth) and dryness of the eyes are often observed with a consequent compromise of oral-motor function and/or functional visual disturbance. If used continuously, the patches tend to lose benefit.

**Hyoscine patch doses and administration**

One patch is normally placed behind the ear where it can be observed for adverse skin reactions.

If the patch is cut the matrix is disrupted and the transdermal efficacy is lost, instead an occlusive dressing is placed on the skin, the patch placed with half over the dressing and then another dressing placed over the patch.

Typically, the patch is replaced every 2–3 days, alternating sites to minimise the risk of a local skin reaction.

- 1 month – 2 year - 250 micrograms ¼ patch every 72 hours
- 3-9 years - 500 micrograms ½ patch every 72 hours
- 10-17 years - 1 mg patch every 72 hours

**Glycopyronium bromide - Sialanar**

Glycopyronium bromide has a well-established history of use over more than 10 years in the United Kingdom for the treatment of drooling.

Sialanar (glycopyronium 320micrograms/ml) equivalent to 400micrograms/ml (2mg/5ml) glycopyronium bromide, was licensed for children throughout Europe in 2016, for the symptomatic treatment of severe drooling aged 3 years and over. It is the first formulation of glycopyronium bromide licensed for this indication in the UK.
Nice guidance refers to 2 small randomised controlled trials (RCTs) compared
glycopyrronium bromide with placebo for the treatment of drooling in children and
young people with chronic neurological conditions. The majority of participants had
cerebral palsy. In both RCTs, participants treated with glycopyrronium bromide had
statistically significantly improved drooling after 8 weeks, compared with placebo.

Adverse effects were common with glycopyrronium bromide, mostly due to its
anticholinergic action, include dry mouth, constipation, urinary retention, reduced
bronchial secretions and flushing. It can cause thickening of secretions, which may
increase the risk of respiratory infection and pneumonia and should be used with
caution in people with heart problems due to its potential increase in heart rate, blood
pressure and rhythm disorders.

Sialanar contains 320 micrograms of the active ingredient, glycopyrronium per ml of
liquid which is EQUIVALENT TO 400 micrograms of the salt glycopyrronium
bromide, per ml.

To effectively treat the symptoms of severe chronic drooling whilst managing
potential side effects, Sialanar should be started at a low dose based on the weight
of the child, starting with approximately 12.8 micrograms/kg glycopyrronium per dose
(equivalent to 16 micrograms/kg glycopyrronium bromide per dose).

This should be given three times per day, increasing by the doses shown in the table
below every 7 days.

Dose titration should be continued until efficacy is balanced with undesirable effects
and amended up or down as appropriate, to a maximum individual dose of 64
micrograms/kg body weight glycopyrronium or 6 ml (1.9 mg glycopyrronium,
equivalent to 2.4 mg glycopyrronium bromide) three times a day, whichever is less.
Dose titrations should be conducted in discussion with the carer to assess both
efficacy and undesirable effects until an acceptable maintenance dose is achieved.

The dose should be given 1 hour before meals or 2 hours after meals. It is important
that the dose is given at consistent times in relation to food intake and not given with
high fat foods.

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**Trihexyphenidyl** (benzhexol, Broflex, Alliance)
This is an oral anticholinergic primarily used in dystonic movement disorders. It reduces Ach release at the basal ganglia level to help improve fluidity of motor control and can be given as a tablet or liquid preparation.

It can be used for children with dyskinetic cerebral palsy, but only with input from specialist services.

**Botulinum toxin type A injections**
Targeted injections of botulinum toxin type A directly into the salivary glands block ACh release, therefore, reducing secretion of saliva.

Quantitative and qualitative benefit is reported for between 1 and 6 months with maximum benefit at 4–6 weeks post-injection. Potential side effects are major, particularly thickening of secretions and dysphagia.

Refer the child or young person to a specialist service if the anticholinergic drug treatments are contraindicated, not tolerated or not effective, to consider other treatments for saliva control.

Consider specialist assessment and use of botulinum toxin A injections to the salivary glands with ultrasound guidance to reduce the severity and frequency of drooling if anticholinergic drugs provide insufficient benefit or are not tolerated.

Advise children and young people and their parents or carers that high-dose botulinum toxin A injection to the salivary glands can rarely cause swallowing difficulties, and so they should return to hospital immediately if breathing or swallowing difficulties occur.

**7.4. Surgery**
A number of different surgical approaches have been used to help with drooling.

Results of drooling surgery in children are variable. Some children gain considerable long-term benefit. For others, there is only a temporary improvement, with consequences of a dry mouth, poor oral hygiene, dental decay and difficulty in chewing.

Consider referring young people for a surgical opinion to Maxillofacial Department at PRH, after an assessment confirming clinically safe swallow, if there is:
- A potential need for lifelong drug treatment or
- Insufficient benefit or non-tolerance of anticholinergic drugs and botulinum toxin A injections.
8.0 Summary and Recommendations

Drooling is a significant issue for a small proportion of the paediatric population.

Improving chronic drooling can help with patient hygiene, reduce secondary infections caused by constant wet and macerated skin and improve patient quality of life and self-esteem.

It is important to take a thorough history and clinical examination and quantification of the problem.

Management of drooling can be conservative/alternative, specific oral-motor exercises, medical, surgical interventions. The overall guiding philosophy is to optimise the quality of life of the child, without compromising oral health.

Consider the use of anticholinergic medication
- Transdermal hyoscine hydrobromide or
- Glycopyrronium bromide (oral or by enteral tube) or
- Trihexyphenidyl hydrochloride for children with dyskinetic cerebral palsy, but only with input from specialist services.

Consider specialist assessment and use of botulinum toxin A injections to the salivary glands with ultrasound guidance to reduce the severity and frequency of drooling if anticholinergic drugs provide insufficient benefit or are not tolerated.

Consider referring young people for a surgical opinion, after an assessment confirming clinically safe swallow, if there is:
- A potential need for lifelong drug treatment or
- Insufficient benefit or non-tolerance of anticholinergic drugs and botulinum toxin injections.
9.0 Consultation

This clinical guideline has been discussed with Community Paediatricians and will be distributed widely for discussion amongst Community Paediatricians.

The following Community Paediatricians were consulted about this guideline:

Dr Ganesh – Consultant Paediatrician
Dr Buch - Consultant Paediatrician
Dr Mahabeer – Consultant Paediatrician
Dr Saran – Consultant Paediatrician
Dr Unsworth – Consultant Paediatrician
Dr Butterworth – Associate Specialist
Dr Posting - Associate Specialist
Dr Ogilvie – Specialty Doctor

10.0 Dissemination and implementation

This clinical guideline will be distributed to relevant staff groups by managers and published on the Trust website.

These guidelines will be disseminated by the following methods:

- Managers Informed via DATIX system who then confirm they have disseminated to staff as appropriate
- Staff via Team Brief
- Published to the staff zone of the trust website

11.0 Monitoring Compliance

Compliance will be monitored by review of any concerns raised about the service by staff or patients.

An audit of the guidelines will be done one year after implementation by Dr Short.
12.0 References

1. Severe sialorrhoea (drooling) in children and young people with chronic neurological disorders: oral glycopyrronium bromide. NICE Evidence summary [ES5] Published date: February 2017


3. Hypersalivation – what drug treatment options are available?. Prepared by UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals. Date prepared: 3rd April 2017

4. NICE guideline - Cerebral palsy in under 25s: assessment and management Published: 25 January 2017. nice.org.uk/guidance/ng62

5. Hypersalivation – what are the treatment alternatives to glycopyrronium and hyoscine? Prepared by UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals. Date prepared: 25th June 2015


12. Hypersalivation – can hyoscine hydrobromide be used to treat it? Prepared by UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals Date prepared: 2nd May 2017
13.0 Appendices

Appendix 1

Modified Teacher's Drooling Scale (mTDS)

The modified Teacher's Drooling Scale (mTDS) is a 9-point scoring system measured by parents/carers.

Scores range from 1 to 9, with a higher score indicates more severe drooling:

1 = Dry: never drools
2 = Mild: only the lips are wet; occasionally
3 = Mild: only the lips are wet; frequently
4 = Moderate: wet on the lips and chin; occasionally
5 = Moderate: wet on the lips and chin; frequently
6 = Severe: drools to the extent that clothing becomes damp; occasionally
7 = Severe: drools to the extent that clothing becomes damp; frequently
8 = Profuse: clothing, hands, tray, and objects become wet; occasionally
9 = Profuse: clothing, hands, tray, and objects become wet; frequently
Appendix 2

The Drooling Rating Scale - Thomas-Stonell and Greenberg classification

Drooling severity
Dry—never drools
Mild—wet lips only
Moderate—wet lips and chin
Severe—damp clothing
Profuse—damp clothing, hands and surrounding objects

Drooling frequency
Never—no drooling
Occasionally Frequently
Constantly
Appendix 3

The Drooling Impact Scale (DIS): a measure of the impact of drooling in children with developmental disabilities

OVER THE PAST WEEK

1. How frequently did your child dribble?
   Not at all | 1 2 3 4 5 5 7 8 9 10 | Constantly

2. How severe was the drooling?
   Remained dry | 1 2 3 4 5 6 7 8 9 10 | Profuse

3. How many times a day did you have to change bibs or clothing due to drooling?
   Once or not at all | 1 2 3 4 5 6 7 8 9 10 | 10 or more

4. How offensive was the smell of the saliva on your child?
   Not offensive | 1 2 3 4 5 6 7 8 9 10 | Very offensive

5. How much skin irritation has your child had due to drooling?
   None | 1 2 3 4 5 6 7 8 9 10 | Severe rash

6. How frequently did your child’s mouth need wiping?
   Not at all | 1 2 3 4 5 6 7 8 9 10 | All the time

7. How embarrassed did your child seem to be about his/her dribbling?
   Not at all | 1 2 3 4 5 6 7 8 9 10 | Very embarrassed

8. How much do you have to wipe or clean saliva from household items, e.g. toys, furniture, computers?
   Not at all | 1 2 3 4 5 6 7 8 9 10 | All the time

9. To what extent did your child’s drooling affect his or her life?
   Not at all | 1 2 3 4 5 6 7 8 9 10 | Greatly

10. To what extent did your child’s dribbling affect you and your family’s life?
    Not at all | 1 2 3 4 5 6 7 8 9 10 | Greatly