Clinical Guideline:
East of England Guideline on the management of Sialorrhoea (excessive salivation, drooling and dribbling)

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For use in: EoE Paediatric Units, Community Paediatrics.

Used by: Community Paediatricians, Paediatricians, ENT surgeons, Respiratory teams, Physiotherapists, Speech, and Language therapists.

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Introduction

Saliva control problems are a major clinical issue, impacting on the quality of life and social interaction for many children and their families. The prevalence of sialorrhoea (excessive salivation, drooling or dribbling) is significant in many children with static or progressive neurological problems, but also frequent in many other neurological conditions (such as epilepsy and autism spectrum disorders) or even as an isolated developmental issue1.
Management should be aimed at addressing the cause which may be multifactorial and patient specific, involving practical aids, speech therapy, physiotherapy, surgery, and medication.

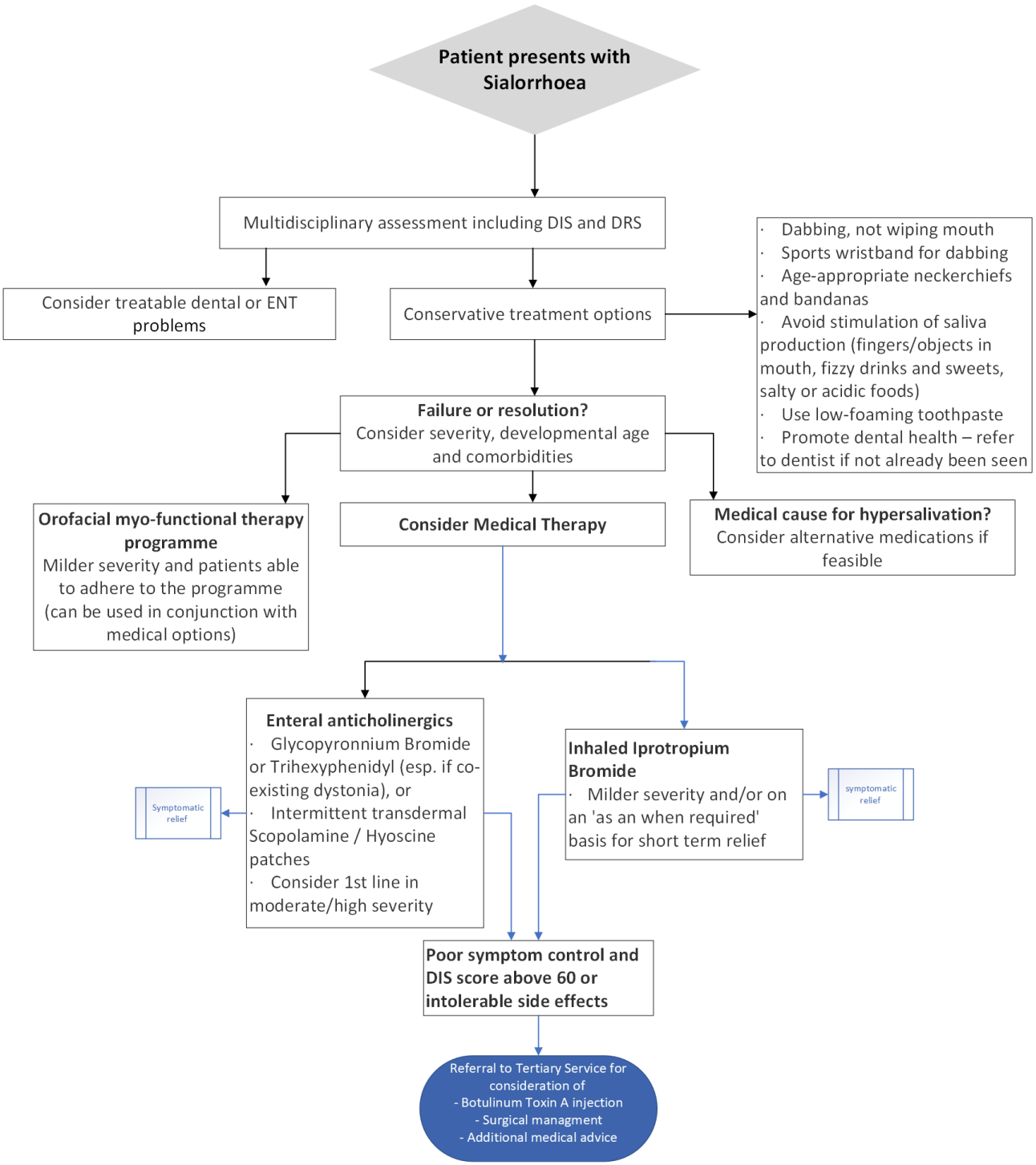
This guideline focuses on the expected good practice standards and the accepted escalation of treatment from community interventions to specialist services. It is in line with The National Institute for Health and Care Excellence (NICE) Cerebral Palsy in under 25s guideline (NG62)[2], the position statement from the American Academy for Cerebral Palsy and Developmental Medicine (AACPDM)[3], and other published literature[1]. The pathway has been agreed with the specialist services of the East of England Region.

A summary of Sialorrhoea management is presented in Figure 1 and guides those managing children with Sialorrhoea through a stepwise approach.

Users of this document in the community should:

- primarily focus on the 'First Line Community Management' section
- use the Drooling Impact Scale (DIS) and Drooling Rating Scale (DRS) to quantify drooling severity and assess efficacy of interventions
- consider referral to tertiary services when appropriate

Figure 1. Summary of Sialorrhoea management



The DIS scores 10 questions related to drooling – frequency, severity, frequency of change of clothing or bibs, smell, irritation, frequency of wiping, personal embarrassment, frequency of wiping objects, as well as impact of drooling on the child and family. These last two subscales represent an important sub-composite for impact of drooling on everyday life for the individual and family (available in Appendix B).

Section 1: First Line Community Management

Children with complex needs who have sialorrhoea should ideally be supported by a multidisciplinary team led by their community Doctor and nursing team with access to Physiotherapy, Occupational therapy, Speech and Language Therapy and Dieticians

First line assessment should assess for factors which may affect drooling
- Positioning including during feeding and play
- Dental disease
- Gastroeosophageal reflux
- Current medication which may increase Sialorrhoea
- ENT conditions e.g. tonsillar hypertrophy

Baseline assessment of symptoms with DIS and DRS score (see Appendix B)

To reduce the severity and frequency of drooling, consider trial of medical therapy which may include:
- glycopyrronium bromide (oral or by enteral tube)
- transdermal hyoscine hydrobromide
- inhaled ipratropium bromide

See appendix A for advice regarding dosing and side effect profiles
Specialist drug treatment with input from Specialist services may include trihexyphenidyl hydrochloride (oral or enteral tube) for children with dyskinetic Cerebral Palsy

Regularly review the effectiveness, tolerability and side effects of all drug treatments used for saliva control titrating the dose of medication according to response and side effects. The DIS and DRS scores repeated at each medication review provide a helpful context for both clinician and care giver to guide level of intervention required.

Referral to a specialist Sialorrhoea clinic for tertiary intervention should be considered if the basic management strategy detailed here has failed to provide symptomatic relief and/or medical therapy is not tolerated due to side effects. See Section 2 for more details.

Note 1: the orofacial myo-functional therapy programme in the flow chart requires a) specialist input from SLT colleagues and should be considered if available, but also b) the cognitive ability of the patient to adhere/ follow the programme itself.

Note 2: sublingual ipratropium bromide can be trialled in milder cases for short-term relief on an 'as and when required' basis. Doses of 20-40 mcg up to QDS/ PRN

Note 3: full details published in J Pediatr. 2024 Feb: 265:113803. doi:10.1016/j.jpeds.2023.113803.[1]

Note 4: In general, glycopyrronium bromide will be considered first line as it is licensed for pathological drooling and easier to titrate with response to avoid side-effects. There is also significant variation in efficacy between individuals with use of hyoscine patches. Advantages and disadvantages between oral glycopyrronium bromide and topical hyoscine are shown in the table below and treatment options should be individualised to specific patient factors.

Glycopyrronium bromide	Hyoscine patches
Advantages: • Licensed for chronic pathological drooling • Long duration of action • Fewer central or cardiac side effects	Advantages: • Ease of administration • Maintenance of steady state concentrations • Lower incidence of systemic side effects compared to other anticholinergics
Disadvantages: • Slower onset	Disadvantages: • Off label indication • May cause drowsiness, dizziness and skin reactions

Section 2: Tertiary Management of Sialorrhoea at CUH

Within the East of England patients Cambridge University Hospital Foundation Trust hosts a Sialorrhoea clinic and referrals are considered from:

1) Community and or secondary care following sufficient trial of basic management and/or intolerable side effects. Triaged by Sialorrhoea team
2) Referral from another Tertiary team

Assessment in the CUH Sialorrhoea clinic will include:

Initial remote video appointment to review history and treatment strategy thus far. Community teams can join this appointment if parental/guardian consent is provided

Treatment may include

1) Botulinum Toxin A injections administered under local anaesthetic and ultrasound guidance (or general anaesthetic if required). This is administered under an NHSE commissioned service who fund the activity costs for administration.
2) Alternative medication trial
3) Referral for surgery under the ENT team

Please address referrals to the CUH paediatric neurology clinic FAO Dr Papandreou.

Appendix A

Medication

Glycopyrronium bromide

Salivation is primarily mediated by parasympathetic innervation of the salivary glands. Glycopyrronium competitively inhibits cholinergic muscarinic receptors in salivary glands and other peripheral tissues, to reduce the rate of salivation.

Other peripheral antimuscarinic effects that can occur are:

- decreased production of secretions from bronchial and sweat glands
- dilatation of the pupils and paralysis of accommodation
- increased heart rate; inhibition of micturition
- reduction in gastrointestinal tone
- inhibition of gastric acid secretion.

First line - Sialanar:

• Sialanar® brand is licensed for chronic pathological drooling in children and adolescents aged 3 years and older with chronic neurological disorders.1,5

Sialanar® dose schedule

Start at 16 micrograms/kg TDS, increasing in steps of 16micrograms/kg TDS every 5-7 days according to response. **Maximum** dose is **80 micrograms/kg TDS** (maximum **2.4mg/dose**). Note that this is lower than the dose for generic glycopyrronium bromide, due to the bioavailability difference.

Weight (kg)	Dose level 1	Dose level 2	Dose level 3	Dose level 4	Dose level 5
	Dose expressed per dose as glycopyrronium bromide and volume as ml of 400microgram/ml solution				
	16 microgram/kg	**32 microgram/kg**	**48 microgram/kg**	**64 microgram/kg**	**80 microgram/kg**
13-17	0.24mg (0.6ml)	0.48mg (1.2ml)	0.72mg (1.8ml)	0.96mg (2.4ml)	1.2mg (3ml) *
18-22	0.32mg (0.8ml)	0.64mg (1.6ml)	0.96mg (2.4ml)	1.28mg (3.2ml)	1.6mg (4ml) *
23-27	0.4mg (1ml)	0.8mg (2ml)	1.2mg (3ml)	1.6mg (4ml)	2mg (5ml) *
28-32	0.48mg (1.2ml)	0.96mg (2.4ml)	1.44mg (3.6ml)	1.92mg (4.8ml)	2.4mg (6ml) *
33-37	0.56mg (1.4ml)	1.12mg (2.8ml)	1.68mg (4.2ml)	2.24mg (5.6ml)	2.4mg (6ml) *
38-42	0.64mg (1.6ml)	1.28mg (3.2ml)	1.92mg (4.8ml)	2.4mg (6ml) *	2.4mg (6ml)
43-47	0.72mg (1.8ml)	1.44mg (3.6ml)	2.16mg (5.4ml)	2.4mg (6ml) *	2.4mg (6ml)
≥48kg	0.8mg (2ml)	1.6mg (4ml)	2.4mg (6ml) *	2.4mg (6ml)	2.4mg (6ml)
*Maximum individual dose at this weight range					

Prescribe as **Glycopyrronium bromide (Sialanar®) 400micrograms/ml*** for all new patients.

*Note the Sialanar® bottle states it contains 320micrograms ***glycopyrronium***/ml which is equivalent to 400micrograms ***glycopyrronium bromide***

Other glycopyrronium bromide brands and formulations:
• There is a difference in bioavailability between Sialanar® brand and generic brands, so it is important to prescribe by brand and follow the dosing recommendation in the BNFC for the correct brand.
• Generic glycopyrronium bromide liquid is also usually a different strength to Sialanar®.
• Glycopyrronium bromide tablets are available for patients unable to take Sialanar® but are not first line due to cost and due to administration difficulties with dosing accuracy.
• If a patient presents taking generic glycopyrronium bromide it is important that the **strength** and **brand** is included on the prescription.
• If existing patients on generic glycopyrronium bromide are switched to Sialanar® ensure that the dose is reviewed and appropriately converted to Sialanar® and the patient/carer is informed of the new volume in mls that needs to be given

• The usual dose for glycopyrronium bromide tablets and **generic** liquid 1mg/5ml oral solution is:

Start at 20micrograms/kg TDS, increasing in steps of 20micrograms/kg TDS every 5-7 days according to response. Maximum dose is 100micrograms/kg TDS (maximum 3mg/dose).

Hyoscine patches

Hyoscine has anticholinergic properties. It competitively inhibits cholinergic muscarinic receptors in salivary glands and other peripheral tissues, to reduce the rate of salivation. Hyoscine patches may provide some advantages over glycopyrronium due to their ease of administration, maintenance of steady state concentrations and where there are swallowing difficulties.

Side-effects include the following: Confusion; constipation; dizziness; drowsiness; dry mouth; dyspepsia; flushing; headache; nausea; palpitations; skin reactions; tachycardia; urinary disorders; vision disorders; vomiting

Hyoscine patch dose

< 3 years: 250micrograms (a quarter of a patch) every 72 hours
3-9 years: 500 micrograms (half a patch) every 72 hours
10 and over: 1mg (1 patch) every 72 hours

• Note that patches contain 1.5mg hyoscine but release 1mg over 72 hours.
• Apply to hairless area of skin e.g. behind ear.
• Some patients may develop tolerance and need patches changing every 48 hours.
• Patches can be cut to give doses less than a whole patch.

Ipratropium bromide

Inhaled ipratropium bromide is a quaternary ammonium derivative of Atropine. It is an anticholinergic compound with bronchodilator properties.
It is used in the management of asthma, and on inhalation, it has an onset of effect within 5–15 min, a peak effect at 1–2 h and a half-life of 3–4 h. Some effect is observed up to 8 h post inhalation
There is a low level of observed systemic side effects, most commonly headache, tachycardia, blurred vision from accommodative problems and gastrointestinal dysmotility. The most common observed "side effect" is drying of the mouth in between 9.3% and 15%. In adult populations, this side effect has been used to some effect to reduce sialorrhoea in individuals with Parkinson's disease. As it is generally well tolerated and easy to give via a nebulised solution, it is a useful adjunct in children.

Ipratropium bromide doses

Formulation	Age	Dose
Aerosol	< 6 years	20 microgram 3 x day
	6 – 12 years	20 – 40 microgram 3 x day
Nebulised solution	< 5 years	125 – 250 micrograms (up to 4 hourly but max 1mg/day)
	> 5 years	250 micrograms (up to 4 hourly but max 1mg/day)

Trihexyphenidyl hydrochloride

Trihexyphenidyl is another anticholinergic agent and also competitively inhibits cholinergic muscarinic receptors in salivary glands and other peripheral tissues, to reduce the rate of salivation. It can be especially considered for patients with co-existing dystonia/ dyskinesia. Side effects include tachycardia, constipation, hallucination and memory impairment.

- Usual dose >1 month age: initially 1-2mg/day in 1-2 doses
- Doses should only be increased by 0.5mg – 1mg per dose per week and stop increase when:
  - Max dose reached (keep on for 3 months and then review)
  - Side-effects – excess constipation, urinary retention, behavioural problems – reduce dose and wait.
  - Benefit achieved without side-effects

1 month – 2 years age	Max dose should not exceed 3mg three times a day
≥2 years age	Max dose should not exceed 6mg three times a day without prior tertiary input

Appendix B

Assessment of Drooling Severity using the Drooling Impact Scale (DIS) and Drooling Rating Scale (DRS)

Drooling Impact Scale (DIS)

OVER THE PAST WEEK

1. How frequently did your child dribble?

Not at all 1 2 3 4 5 6 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

Drooling Rating Scale—Thomas-Stonell and Greenberg

Drooling severity:

1. Dry—never drools
2. Mild—wet lips only
3. Moderate—wet lips and chin
4. Severe—damp clothing
5. Profuse—damp clothing, hands and surrounding objects

Drooling frequency:

1. Never—no drooling
2. Occasionally
3. Frequently
4. Constantly

The DRS scores severity of saliva control problems out of 5 – 1 being dry and 5 being profuse; as well as frequency out of 4 – 1 never and 4 constant.

When using the DIS and DRS, the strength of benefit or effect size is set out for changes observed following intervention. A minimal clinically important of difference in the score of over 10 is reported as ‘reliable’; one of 20-28 a ‘good’ outcome; and one over 28-38 ‘very good to excellent’. With the DRS, a reduction of 1 in frequency and severity was considered by NICE to be clinically significant.

Appendix C

Medication cost

Drug	Cost	Average dose	Cost per day	Cost per 28 days	Excipient comments	General comments
Sialanar (glycopyrronium bromide) 2mg/5mL oral solution.	£320.00 / 250mL	At dose level 3 1.44mg (3.6mL) 3 times day	£13.82	£386.96	Contains sodium benzoate 2.3mg/mL Max dose of 80mcg/kg/dose 3 x day would give 1.38mg/kg/day which is well below acceptable level of 5mg/kg/day benzoate.	Shelf life 2 months after opening
Glycopyrronium bromide 1mg/5mL oral solution (Colonis)	£91.00 / 150mL	At dose level 3 1.8mg (9mL) 3 times day	£16.38	£458.64	Contains: Sorbitol 175mg/mL Parabens Sorbitol is associated with GI symptoms	Shelf life 28 days after opening
Glycopyrronium tablets 1mg	£135.57 / 30 tabs (Alliance)	At dose level 3 1.8mg 3 times a day	£27.11	£759.08	Contains lactose	Tablets may need to be dispersed in water and aliquot withdrawn for required dose – possible issues with dosing accuracy
Glycopyrronium tablets 2mg	£158.93 / 30 tabs (Alliance)	At dose level 3 1.8mg 3 times a day	£15.89	£444.92	Contains lactose	Tablets may need to be dispersed in water and aliquot withdrawn for required dose – possible issues with dosing accuracy
Hyoscine patches 1mg/24hr	£12.87 / 2 patches	Half a patch every 72 hours	£3.22 per 3 days	£32.20	N/A	Costs based on other half of patch being kept for next dose.
Ipratropium bromide 20mcg/puff inhaler 200 doses	£5.56 / inhaler	20 mcg 3 times a day	£0.08	£2.24	N/A	
Ipratropium bromide 250 mcg/2mL nebuliser solution	£4.14 / 20 nebules	250 mcg 3 times a day	£0.62	£17.39	N/A	
Trihexyphenidyl tablets 2mg	£3.14 / 84 tabs	4mg 3 times a day	£0.22	£6.16		
Trihexyphenidyl tablets 5mg/5mL oral solution	£108.44 / 200mL	4mg 3 times a day	£6.51	182.28	Contains: Ethanol 0.817mg/5mL Propylene glycol 19.27mg/5mL Sodium benzoate 5.9mg/5mL (all below acceptable levels)	
Botox botulinum toxin 100-unit vial	£138.20 / vial	Max 1 vial 2 x year	-	£276.40 per annum	N/A	Hospital only
Dysport botulinum toxin 500-unit vial	£154.00 / vial	Max 1 vial 2 x year	-	£308 per annum	N/A	Hospital only
Xeomin botulinum toxin 100-unit vial	£90 / vial	Max 1 vial 2 x year	-	£180 per annum	N/A	Hospital only Xeomin is the only product licensed for chronic sialorrhoea

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