

SHARED CARE GUIDELINE FOR SSRIs for the treatment of DEPRESSION, OBSESSIVE COMPULSIVE DISORDER and ANXIETY in CHILDREN and YOUNG PEOPLE

1. Aim/Purpose of this Guideline

1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of SSRIs for depression, OCD and anxiety in children and young people.

2. The Guidance

2.1. See below for the Shared Care Guideline.

SELECTIVE SEROTONIN RE-UPTAKE INHIBITORS (SSRIs)

This shared care guideline sets out details for the sharing of care of children and young people affected by major depression, anxiety or obsessive compulsive disorder (OCD) requiring pharmacological treatment. These guidelines provide additional information necessary to aid in the treatment of these patients. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF-C, ABPI summary of product characteristics and **do not** replace them.

In 2000, the Royal College of Paediatrics and Child Health issued a policy statement on the use of unlicensed medicines or the use of licensed medicines for unlicensed applications, in children and young people. This states clearly that such use is necessary in paediatric practice and that doctors are legally allowed to prescribe unlicensed medicines where there are no suitable alternatives and where the use is justified by a responsible body of professional opinion. In December 2003, the Committee on Safety of Medicines advised that the balance of risks and benefits was favourable only for fluoxetine in treatment of major depression in under 18 year olds.

The CSM also went on to accept that on occasion, psychiatrists may use other SSRIs when patients have not tolerated or responded to fluoxetine. The risk versus benefit assessment and informed discussion with young person and carer would be managed by the responsible psychiatrist. The lack of wider clinical trials on medicines for major depression in the childhood population is recognised as adding to the limitation in evaluating their safety and efficacy. The CSM warnings apply only to major depression and not to other disorders treated with SSRIs.

Summary of the studies considered by the NICE Childhood Depression Working Group and by the Medicines and Health Products Regulatory Agency (MHRA) suggested:

- **fluoxetine** has consistent evidence of clinical improvement across a range of outcome measures.
- **sertraline** and **citalopram** have more limited and inconsistent evidence for clinical improvement, but the risk / benefit ratio is less unfavourable than for the remaining SSRIs.

INDICATIONS FOR THE PURPOSES OF THIS GUIDELINE

DEPRESSION

NICE guidance recommends that medication for moderate to severe childhood depression only, which is unresponsive to psychological therapy after 4-6 sessions, and after specialist assessment. Concurrent psychological therapy and review is recommended alongside any medication.

Antidepressant medication is recommended for children aged 12-18 years; fluoxetine may be prescribed to

children from 5 years with extreme caution. However, it is licensed for children of 8 years of age and above.

1st line option – fluoxetine

2nd line option – sertraline or citalopram

ANXIETY

CBT would normally be first line therapy for anxiety as a standalone presentation. However if pharmacological management is deemed appropriate and necessary, SSRIs are a first-line choice but have a limited evidence base.

Options – sertraline or citalopram depending on patient preference

OBESSESSIVE COMPULSIVE DISORDER

If psychological treatment (CBT with ERP) is declined by children or young people with OCD and their families or carers, or they are unable to engage in treatment, an SSRI may be considered. Current published evidence suggests that SSRIs are effective in treating children and young people with OCD. The only SSRIs licensed for use in children and young people with OCD are fluvoxamine and sertraline.

1st line option – sertraline

2nd line option - fluvoxamine

Specialist Services will offer patients SSRIs for moderate to severe depression, anxiety or OCD after assessment and where psychological therapy alone is insufficient (or unavailable). They will undertake informed discussion about risks and benefits of proposed treatment with the young person and carers. Specialist Services will provide advice on choice of drug, initiation, titration and monitoring. Monitoring clinical outcomes and side effects will generally take place in secondary care specialist mental health services.

PREPARATION & DOSAGE FOR ALL INDICATIONS

SSRI & INDICATION	DOSAGE RANGE	FORMULATION
Fluoxetine-Depression (licensed) 1st line	Child 8-17 years: 10mg once daily. Increased if necessary after one-two weeks. Max. 20mg once daily. NOTE: higher doses up to 40mg once daily may be considered in older children of higher body weight.	<ul style="list-style-type: none"> • Capsules • Liquid <p>Dispersible tablets are available but are non-formulary</p>
Sertraline - Depression (unlicensed) 2 nd line	Child 12-17 years: 50mg once daily. Increased if necessary in steps of 50mg at intervals of at least a week. Max. 200mg once daily.	<ul style="list-style-type: none"> • Tablets <p>Suspensions/solutions are available as unlicensed specials and are very expensive.</p>
Sertraline – OCD Anxiety (licensed) (unlicensed)	Child 6-11 years: 25mg daily initially, increased to 50mg daily after one week. Further increased if necessary in steps of 50mg at intervals of at least 1 week. Max. 200mg once daily. Child 12-17 years: 50mg daily initially, increased if necessary in steps of 50mg over several weeks. Max. 200mg once daily.	
Citalopram-Depression (unlicensed) 2 nd line	Child 12-17 years: Tablets: 10mg once daily. Increased if necessary to 20mg over two-four weeks. Max. 40mg once daily Drops: 8mg once daily increased if necessary to 16mg once daily over two-four weeks. Max. 32mg once daily. (four oral drops (8mg) =10mg tablet)	<ul style="list-style-type: none"> • Tablets • Oral drops <p>(drops can be mixed with water, orange or apple juice)</p>
Citalopram – Anxiety (unlicensed)	Child 12- 17 years: 10 mg once daily increasing in 10mg increments no faster than weekly to 20mg Max. 40mg daily Drops: 8mg once daily increased if necessary to 16mg no faster than weekly. Max. 32mg once daily.	
Fluvoxamine-OCD (licensed)	Child 8-17 years: Initially 25 mg daily, increased in steps of 25 mg every 4–7 days if required (max. per dose 100 mg twice daily) if required. Doses above 50 mg should be given in 2 divided doses, if no improvement within 10 weeks, treatment should be reconsidered.	<ul style="list-style-type: none"> • Tablets <p>Suspensions are available as unlicensed specials</p>

Criteria for 2nd line treatment:

- persistent clinical severity.
- ineffective trial of 1st line treatment.
- reasonable exclusion of other likely causes of treatment resistance.
- following peer review or 2nd opinion from CAMHS specialist team.
- informed discussion with child/ carer

MONITORING

Patients should be reviewed every 1–2 weeks at the start of antidepressant treatment. Treatment should be continued for at least 4 weeks before considering whether to switch SSRI due to lack of efficacy. In cases of partial response, continue for a further 2–4 weeks.

Following remission, SSRI treatment should be continued at the same dose for at least 6 months. Patients with a history of recurrent depression should receive maintenance treatment for at least 2 years.

Hyponatraemia has been associated with all types of antidepressants; however, it has been reported more frequently with SSRIs than with other antidepressants. Hyponatraemia should be considered in all patients who develop drowsiness, confusion, or convulsions while taking an antidepressant.

CONTRAINDICATIONS AND PRECAUTIONS

Please also refer to current BNF and SPC.

Contra-indications – current episode mania

Cautions - SSRIs should be used with caution in patients with:

- epilepsy (avoid if poorly controlled, discontinue if convulsions develop),
- cardiac disease
- diabetes mellitus
- susceptibility to angle-closure glaucoma
- a history of mania
- history of bleeding disorders (especially gastrointestinal bleeding), and if used with other drugs that increase the risk of bleeding.

They should also be used with caution in those receiving concurrent electroconvulsive therapy (prolonged seizures reported with fluoxetine).

SSRIs may also impair performance of skilled tasks (e.g. driving)

CSM advice on risk of suicidal behaviour in young adults with depression:

Careful and frequent patient monitoring by healthcare professionals, and where appropriate other carers, is important in the early stages of treatment, particularly if a patient experiences worsening of symptoms or if new symptoms arise after starting treatment.

If a patient is not doing well after starting treatment the possibility of an adverse reaction to the drug should be considered. Patients should be monitored for signs of restlessness or agitation, particularly at the beginning of treatment. Increasing the dose in these circumstances may be detrimental.

Patients should be monitored around the time of dose changes for any new symptoms or worsening of disease. To minimise withdrawal reactions on stopping SSRIs, the dose should be tapered gradually over a period of several weeks, according to the patient's need.

SIDE EFFECTS

Please also refer to current BNF and SPC

- gastro-intestinal effects (dose-related and fairly common – include nausea, vomiting, dyspepsia, abdominal pain, diarrhoea, constipation),
- anorexia with weight loss (increased appetite and weight gain also reported)
- hypersensitivity reactions
- dry mouth, urinary retention, sweating
- nervousness, anxiety
- headache, insomnia, hallucinations, drowsiness
- dizziness, asthenia
- galactorrhoea, sexual dysfunction
- hypomania or mania (see Cautions above),
- convulsions (see Cautions above), movement disorders and dyskinesia
- visual disturbance
- hyponatraemia should be suspected in anyone with drowsiness, confusion, nausea, cramps or seizures.
- bleeding disorders

INTERACTIONS

Please also refer to current BNF and SPC

- Anti-epileptics
- An SSRI or related antidepressant should not be started until 2 weeks after stopping a monoamine oxidase inhibitor (MAOI). Conversely, an
- MAOI should not be started until at least a week after an SSRI or related antidepressant has been stopped (2 weeks in the case of sertraline, at least 5 weeks in the case of fluoxetine)
- St John's Wort.
- Fluoxetine inhibits the hepatic cytochrome P450 2D6 enzyme.
- Concomitant therapy with drugs also metabolised by this enzyme system may lead to drug interactions.
- Sertraline and citalopram are weak inhibitors of cytochrome P450 enzyme, so interactions with other drugs are possible.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

These are suggested ways in which the responsibilities for the management of children and young people who are prescribed SSRIs can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

In its guidelines on responsibility for prescribing (circular EL(91)127) between hospitals and GPs, the DH has advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

Referral criteria:

The patient will have received at least 6 weeks treatment and been shown to respond to the treatment and the dosage stabilised, before prescribing is transferred to the GP.

Specialist responsibilities:

- Direct assessment or supervision of specialist team assessment, evaluation of prior treatment, and rationalisation of treatment with appropriate SSRI.
- Informing patient/ carer of diagnosis, care plan, treatment including side effects and use of unlicensed product. Use of Patient Information Leaflets (PILs), user-friendly information leaflets for children/adolescents.
- Treatment decisions should be shared between patient, carer and the Specialist.
- Informing young person/ carers of the latest regulatory advice.
- Ascertaining patient/ family's commitment to safe storage and handling of medication.
- Asking General Practitioners (GP) if they are willing to participate in shared care.
- Initiation and titration of SSRI to a suitable dose or supplying instructions/directions to the GP for initiation and titration of SSRI to a suitable dose.
- Written correspondence to GP from Specialist Team, summarising progress and recommendations for continued treatment.
- Ensure clear arrangements for GP back up, advice and support.
- To inform young person/ carer of the risk of mood or physical side-effects, particularly around initiation and cessation of treatment.
- Monitoring response to treatment, and adverse effects.
- Ensure patients are monitored for suicidal behaviour, self-harm or hostility particularly at the beginning of treatment.
- A person with depression started on antidepressants who is considered to present an increased suicide risk should normally be reviewed after one week and frequently thereafter as appropriate until the risk is no longer considered clinically significant.
- Ensuring concurrent psychological therapy is offered.
- If one is needed, use a recognised self-report rating scale such as the Mood and Feelings Questionnaire (MFQ).
- Promoting access to any appropriate supporting therapies, carer education, and appropriate school liaison.
- Minimum 6 monthly Specialist review appointments.
- Reporting suspected adverse drug reactions to the MHRA.
- Discontinuation of treatment, (or transfer if appropriate).

General Practitioner responsibilities:

- Replying to requests for shared care as soon as possible.
- Titration of SSRI / continued prescribing of SSRI in the community under guidance of Consultant/ Specialist Team.
- Refer to the Consultant/Specialist Team for queries regarding treatment/side effects, and concerns about compliance or suspected drug misuse.
- To be aware of the risk of mood or physical side effects, particularly around initiation and cessation of treatment.
- Ensure compatibility of SSRI with concomitant prescribed medication.
- Stopping treatment on the advice of the Consultant/Specialist team.

Patient and parent / carer responsibilities:

- Agree to request prescriptions from the GP in good time; obtain the first GP prescription within 2 weeks of being informed that shared care will be in operation.
- Report any concerns or adverse effects to the GP, Consultant or Pharmacist.
- Patient information leaflet can be found in Appendix 1 of this document.

BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM THE RELEVANT CLINICAL TEAM

Request for other formats



Please ask if you would like to receive this leaflet in large print, braille, on CD or in any other languages. If you would like the leaflet in an alternative format please contact the NHS Kernow Communications Team at communications@kernowccg.nhs.uk or call 01726 627800

REFERENCES

1. Joint Royal College of Paediatrics and Child Health/Neonatal and Paediatric Pharmacists Group Standing Committee on Medicines, 2000.
2. MHRA – Overview of regulatory status and CSM advice relating to MDD in children and adolescents 2005
3. NICE Clinical Guideline 28: Depression in children and young people: Identification and management in primary, community and secondary care (September 2005)
4. NICE Clinical Guideline 31: Obsessive compulsive disorder and body dysmorphic disorder: treatment (November 2005)
5. BNF
6. BNF for Children
7. Summary of Product Characteristics. www.medicines.org.uk
8. Medicines for Children. www.medicinesforchildren.org.uk

SSRIs – Information for patients, parents and carers

Appendix 1

What are SSRIs?

SSRIs increase the activity of a chemical called serotonin in the brain. They help to reduce the symptoms of depression, and improve mood and behaviour. It takes some time for these medicines to work. It is important that you continue to give/take it regularly, even if you think it isn't helping.

How should SSRIs be taken?

SSRIs are usually given once each day. This is usually in the morning. Give the medicine at about the same time each day so that this becomes part of your child/young person's daily routine, which will help you to remember. Your doctor will work out the amount of fluoxetine (the dose) that is right for your child. The dose will be shown on the medicine label. Usually your child will start on a low dose of SSRI medicine. Your doctor may increase this dose later, if they think this is necessary.

Fluoxetine is available as capsules, liquid and dispersible tablets:

Capsules should be swallowed with a glass of water, milk or juice. Your child should not chew the capsule. Dispersible (Olena) tablets can be swallowed whole with a glass of water or fruit juice. Your child should not chew the tablet. You can disperse the tablet in water. Your doctor or pharmacist will tell you how much liquid to use, and how much to give your child. Make sure your child drinks it all straight away. Do not crush the tablet. Liquid medicine: Measure out the right amount using a medicine spoon or oral syringe. You can get these from your pharmacist. Do not use a kitchen teaspoon as it will not give the right amount.

Sertraline is available as tablets:

Tablets should be swallowed with a glass of water, milk or juice. Your child should not chew the tablet. If your child is unable to swallow the tablets please discuss with your child's GP.

Citalopram is available as tablets and oral drops (liquid):

Tablets should be swallowed with a glass of water, milk or juice. Do not chew them (they have a bitter taste).

Oral Drops: Count the required number of drops into a drink of water/juice. Stir it briefly and then drink all of it.

Fluvoxamine is available as tablets:

Tablets should be swallowed with a glass of water, milk or juice. If your child is unable to swallow the tablets please discuss with your child's GP.

Do SSRIs have any side effects?

Your child may have the following side-effects when they first start taking the medication. These usually wear off after a few days as your child's body gets used to the medicine. If they continue to be a problem after a week, contact your doctor.

- Your child may get indigestion, stomach ache, feel sick or be sick (vomit). Giving each dose with some food may help.
- Your child may get diarrhoea or constipation (difficulty doing a poo). They may have difficulty passing urine (doing a wee).
- They may have a headache.
- They may have difficulty sleeping or have nightmares, or they may feel more sleepy and tired than normal.
- Fluoxetine can affect the ability to do skilled tasks such as driving, riding a bicycle or playing sports. Your child should take care when doing tasks that require co-ordination until they get used to the medicine.
- They may feel more or less hungry than usual – tell your doctor if your child appears to have gained or lost a lot of weight.
- They may have difficulty swallowing. Try giving your child soft food to eat.
- They may have a dry mouth, or a metallic or bitter taste in the mouth – eating citrus fruits (oranges), taking sips of water or sucking on sugar-free boiled (hard) sweets may help.
- They may produce a milky substance from the nipples. This is nothing to worry about. Contact your doctor if this happens.
- Your child's skin will be more sensitive to sunlight. Keep them out of strong sun. When outdoors, they should wear a long-sleeved top, trousers and a hat and should use a high-factor sun screen (at least SPF 30). They should not go on a tanning bed.

The following side effects are more serious and you should seek medical advice immediately:

- If your child seems confused or agitated and has a fever (temperature above 38°C), muscle stiffness and a rapid heartbeat, take them to hospital or call an ambulance straight away. They may have a rare but serious reaction called serotonin syndrome.
- If your child gets swelling of the eyes, face or lips, a rash, redness, itchiness, blistering or peeling of the skin, or has difficulty breathing, take them to your doctor or hospital straight away. They may be allergic to the medication.
- Very rarely, SSRIs can cause seizures (convulsions or fits). If your child has a seizure, telephone for an ambulance. Do not restrain your child, but try to make sure that they cannot hurt themselves (e.g. put a cushion under their head and move them away from furniture).
- If your child has trouble focusing, seems confused, unsteady or disorientated, or has hallucinations (seeing things that are not there), contact your doctor straight away.
- If your child feels very low or suicidal, tense, nervous, worried or on edge, please contact your doctor.

Do SSRIs interact with other medicines?

You can give your child medicines that contain paracetamol or ibuprofen, unless your doctor has told you not to. SSRIs should not be taken with some common drugs that you get on prescription. It is important to tell your doctor and pharmacist about any other medicines your child is taking before starting the SSRI. Check with your doctor or pharmacist before giving any other medicines to your child. This includes herbal or complementary medicines.

Where can I obtain further information?

You can obtain further information from your child's consultant.

3. Monitoring compliance and effectiveness

Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice)
Lead	Head of Prescribing Support Unit
Tool	No specific tool
Frequency	As required according to clinical incident reports
Reporting arrangements	Via Medicines Practice Committee
Acting on recommendations and Lead(s)	Relevant Clinical Staff
Change in practice and lessons to be shared	Relevant Clinical Staff

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ['Equality, Diversity & Human Rights Policy'](#) or the [Equality and Diversity website](#).

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Shared Care Guideline for SSRIs for depression, OCD and anxiety in children and young people.		
Date Issued/Approved:	September 2017		
Date Valid From:	September 2017		
Date Valid To:	September 2020		
Directorate / Department responsible (author/owner):	CAMHs Team M Wilcock, Head of Prescribing Support Unit, Pharmacy Department, RCHT		
Contact details:	01872 253548		
Brief summary of contents	Some clinical issues and details of prescribing responsibilities for GP and specialists		
Suggested Keywords:	Shared care		
	RCHT	CFT	KCCG
	✓	✓	✓
Executive Director responsible for Policy:	Medical Director		
Date revised:			
This document replaces (exact title of previous version):	New document		
Approval route (names of committees)/consultation:	Cornwall Area Prescribing Committee		
Divisional Manager confirming approval processes	Not required		
Name and Post Title of additional signatories			
Signature of Executive Director giving approval	{Original Copy Signed}		
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only
Document Library Folder/Sub Folder	Clinical / Pharmacy		
Links to key external standards	None		
Related Documents:	None		
Training Need Identified?	No		

Version Control Table

Date	Version No	Summary of Changes	Changes Made by <i>(Name and Job Title)</i>

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

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Appendix 2. Initial Equality Impact Assessment Screening Form

Name of service, strategy, policy or project (hereafter referred to as <i>policy</i>) to be assessed: Shared care guideline for SSRIs for depression, OCD and anxiety in children and young people.	
Directorate and service area: Pharmacy	Is this a new or existing Procedure? New
Name of individual completing assessment: Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow	Telephone: 01726 627953
1. Policy Aim*	To provide information on prescribing of SSRIs in children and young people to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives*	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area)
3. Policy – intended Outcomes*	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
5. How will you measure the outcome?	If the guideline is not well received, publicised and adopted, then some GPs may not enter into shared care arrangements.
5. Who is intended to benefit from the Policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.
6a. Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? b. If yes, have these groups been consulted? c. Please list any groups who have been consulted about this procedure.	No Cornwall & IoS Area Prescribing Committee

7. The Impact			
Please complete the following table.			
Are there concerns that the policy could have differential impact on:			
Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		✓	
Sex (male, female, trans-gender / gender reassignment)		✓	
Race / Ethnic communities / groups		✓	

Disability - learning disability, physical disability, sensory impairment and mental health problems		✓	
Religion / other beliefs		✓	
Marriage and civil partnership		✓	
Pregnancy and maternity		✓	
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		✓	
<p>You will need to continue to a full Equality Impact Assessment if the following have been highlighted:</p> <ul style="list-style-type: none"> • You have ticked “Yes” in any column above and • No consultation or evidence of there being consultation- this <u>excludes</u> any <i>policies</i> which have been identified as not requiring consultation. or • Major service redesign or development 			
8. Please indicate if a full equality analysis is recommended.		Yes	No ✓
9. If you are not recommending a Full Impact assessment please explain why.			
Signature of policy developer / lead manager / director		Date of completion and submission	
Names and signatures of members carrying out the Screening Assessment	1. Dan Thomas 2. Mike Wilcock		

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed _____ Dan Thomas and Mike Wilcock _____

Date __September 2017____