South Staffordshire and Shropshire Healthcare NHS
NHS Foundation Trust
A Keele University Teaching Trust

Essential Shared Care Agreement:
Fluoxetine in Children & Adolescents

Please complete the following details:
Patient's name, address, date of birth, and either complete when the consultant will review, OR duration of treatment and suggested date for GP review
Consultant's contact details (p.3)
And send One copy to:
-the patient's GP
-put one copy in care plan
-give one copy to the patient

Patient's name:	
Patient's address:	
Patient's Date of Birth:	
Consultant Review:	
Duration of Treatment/ GP Review due:	

Note:
Guidelines will only be written when it has been agreed (at the Medicines Management Committee) that shared care is or maybe an appropriate option in individual cases, and will include a statement of Specialist Unit /GP responsibilities.

Shared Care Guidelines will ensure that all GPs have sufficient information to enable them to undertake responsibility for specialist therapies and other therapies which may affect/interact with specialist therapies.

It is not the intention to insist that GPs prescribe such a therapy and any doctor who does not wish to undertake the clinical and legal responsibility for a Shared Care Drug is not so obliged. Acceptance of the Shared Care Guidelines will be endorsed by the prescribing departments of the CCG.

The information contained in this guideline is issued on the understanding that it is the best available from the resources at our disposal at the time of issue. For further information please refer to the relevant Summary of Product Characteristics and NICE guidance or contact your local Specialist or Drug Information Centre.

Further copies of this guideline may be obtained from:

- South Staffordshire & Shropshire Healthcare Foundation NHS Trust
- PCT Prescribing Advisers.

Produced: December 2015
Review date: December 2017

SHARED CARE GUIDELINES FOR FLUOXETINE IN CHILDREN & ADOLESCENTS

Referral Criteria

- In some cases, prescribing will have been initiated by a GP, and in these cases, shared care is not appropriate, and prescribing responsibility remains with the GP.
- When initiation is by the Trust, and is required immediately, the patient will receive supplies of Antidepressants on a hospital or community prescription form (usually for 2 weeks) until shared care is appropriate and agreed
- The patient will have an individual care programme agreed with them. A named key worker will have been organised and mental health team input organised.

Specialist Services Responsibilities

- Assess the patient, establish a diagnosis and determine a management strategy to include the roles of different professionals
- Discusses carefully the risks and benefits of treatment with the child/young person and/or their parents
- Undertake baseline monitoring of any parameters considered necessary to start the therapy, and communicate these to the GP, or agree with the GP that they undertake these (none usually required).
- Ensure that the key worker has drawn up a Care Programme and communicated this to the GP
- Send a letter to the GP suggesting that the patient's condition now seems appropriate for a shared care approach, and that shared care is assumed to be formally agreed for this patient.
- If the antidepressant has been initiated, the patient will receive supplies of Antidepressants from the hospital to last for two weeks from the date of the letter.
- Specialist services will review the patient as appropriate, monitoring for the occurrence of mania/hypomania, suicidal ideation, self-harm
- Alteration of (or advice about): antidepressants dosage (particularly during initiation phase), and discontinuation according to clinical parameters.
- Evaluation of adverse events reported by the GP, and identification of any specific monitoring required.

GP Responsibilities

- If the GP declines shared care he/she will notify the consultant without undue delay
- Monitoring the patient's overall health and well-being
- Prescribing Antidepressants, and dosage adjustment as advised by the specialist
- Discontinuing after advised duration period and reviewing the medication as advised by the specialist (e.g. after dosage adjustment, and later every 6 months)
- Adverse drug reaction/Interaction monitoring
- Keeping the key worker/mental health team informed of progress

- Inform specialist of all relevant medical information regarding the patient and any changes to the patient's medication irrespective of indication.

Back-up advice on the above is available at all times:
South Staffordshire & Shropshire Healthcare Foundation NHS Trust – Contact Details

Contact	Speciality	Available	☎	Pharmacy
Dr		Mon-Fri 8.30 – 5.00		01785 783118

Fluoxetine in Children & Adolescents - Additional Prescribing Information

Background

Suicide-related behaviours (suicide attempt and suicidal thoughts) and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. Fluoxetine should only be used in children and adolescents aged 8 to 18 years for the treatment of moderate to severe major depressive episodes and it should not be used in other indications. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms.

The MHRA has issued guidance on the safety of SSRIs in the treatment of depression in children and adolescents, and the level 1 guidance is summarised below (levels 2-3 guidance can be found on http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON019494:

Level 1 - Overview of regulatory status and CSM advice relating to major depressive disorder (MDD) in children and adolescents

Introduction

The MHRA arranged the guidance into three levels of detail:

› Level 1: Overview of regulatory status and CSM advice relating to major depressive disorder (MDD) in children and adolescents.

› Level 2: Summary of available safety and efficacy data in MDD in children and adolescents.

› Level 3: Summary of clinical trials relating to MDD in children and adolescents

Overview of regulatory status and CSM advice relating to major depressive disorder (MDD) in children and adolescents

	Fluoxetine	Sertraline	Citalopram	Escitalopram	Fluvoxamine	Paroxetine	Venlafaxine	Mirtazapine
Drug class	SSRI	SSRI	SSRI	SSRI (active constituent of citalopram)	SSRI	SSRI	Serotonin and noradrenaline reuptake inhibitor (SNRI)	Noradrenergic and specific serotonergic antidepressant
Licensed indications children and adolescents	None	Obsessive compulsive disorder	None	None	Obsessive compulsive disorder	None	None	None
Efficacy in major depressive disorder (MDD) in children and adolescents	Demonstrated in controlled clinical trials	Not demonstrated in controlled clinical trials	Not consistently demonstrated in controlled clinical trials	No data from clinical trials	No data from clinical trials	Not demonstrated in controlled clinical trials	Not demonstrated in controlled clinical trials	Not demonstrated in controlled clinical trials

	Fluoxetine	Sertraline	Citalopram	Escitalopram	Fluvoxamine	Paroxetine	Venlafaxine	Mirtazapine
Safety profile in MDD trials in children and adolescents	Mania and hypomania more frequently reported than in adults, perhaps as a result of differing inclusion criteria in clinical trials. No increased rate of self-harm and suicidal thoughts compared with placebo	Rate of events including agitation, anorexia, insomnia and suicidal thoughts and self harm increased compared with placebo	Increased rate of self-harm compared with placebo in 1 of 2 trials	No data from clinical trials	No data from clinical trials	Increased rate of self-harm and suicidal thoughts compared with placebo	Increased rate of self-harm and suicidal thoughts compared with placebo	No increased rate of self-harm and suicidal thoughts compared with placebo
CSM advice in relation to MDD in children and adolescents	Risk/benefit balance is favourable	Risk/benefit balance is unfavourable	Risk/benefit balance is unfavourable	Risk/benefit balance is presumed unfavourable. (Extrapolation from citalopram.)	Risk/benefit balance is not assessable - safety and efficacy in adults cannot be extrapolated to under 18 year olds	Risk/benefit balance is unfavourable	Risk/benefit balance is unfavourable	Risk/benefit balance is unfavourable

Ask about side effects at every consultation.

Consider suicidal ideation, self-harm, mania, hypomania.

Only limited evidence is available concerning long-term effect on safety in children and adolescents, including effects on growth, sexual maturation and cognitive, emotional and behavioural developments

In a 19-week clinical trial, decreased height and weight gain was observed in children and adolescents treated with fluoxetine. It has not been established whether there is an effect on achieving normal adult height. The possibility of a delay in puberty cannot be ruled out. Growth and pubertal development (height, weight, and TANNER staging) should therefore be monitored during and after treatment with fluoxetine. If either is slowed, referral to a paediatrician should be considered.

In paediatric trials, mania and hypomania were commonly reported. Therefore, regular monitoring for the occurrence of mania/hypomania is recommended. Fluoxetine should be discontinued in any patient entering a manic phase.

It is important that the prescriber discusses carefully the risks and benefits of treatment with the child/young person and/or their parents.