South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

ESSENTIAL SHARED CARE AGREEMENT FOR Risperidone, Olanzapine, Quetiapine, Aripiprazole, or Amisulpride for Behavioural indications in DNLD

Please complete the following details:

Patient's name, address, date of birth
Consultant's contact details (p.3)
And send One copy to:

1. ***the patient's GP***
2. ***put one copy in care plan***
3. ***give one copy to the patient***

Patient's name:	
NHS Number:	
Patient's address:	
Patient's Date of Birth:	
As of this date: Please add to repeat prescription	
Medication prescribed: Dose:	

The aim of this shared care agreement is to provide information on the responsibilities of the General Practitioner and the Consultant while sharing the care of patients prescribed medicines covered by the shared care agreement.

Guidelines will only be written when it has been agreed that shared care is an appropriate option, 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. (It should be noted that it is inappropriate to decline the invitation to shared care on the grounds of cost alone).Acceptance of the Shared Care Guidelines will be endorsed by the Medicines Management Teams of the CCGs.

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
- CCG Prescribing Advisers.

Produced: April 2016. Review date: April 2018. Replaces E037

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 specialist prescribers in the DNLD services for the Trust, it may be for an unlicensed indication in people presenting with behavioural problems; this may be in different circumstances:
    1. licensed use in people who have e.g. schizophrenia or mania who present with behavioural problems
    2. off label use where a clear diagnosis of mental illness can not be made due to the severity of the learning disability, or,
    3. where, e.g. a condition such as anxiety secondary to autism is diagnosed but the anxiety is not caused by schizophrenia
- The patient will receive supplies of the antipsychotic on a hospital or community prescription form until shared care is appropriate and agreed. The potential trigger for shared care is when the patient appears stable since the last review, i.e. no change in mental state, no significant changes in medication and no episodes on inpatient treatment.

Specialist Services Responsibilities

- Assess the patient, establish a diagnosis and determine a management strategy
- Baseline tests will be the responsibility of the specialist before transfer to shared care. See Appendix 2. Undertake baseline monitoring and communicate results to the GP, or agree with the GP that they undertake these (according to local arrangements).
- 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, unless the practice respond differently within 2 weeks. Communicate to the GP, monitoring results to date, and what needs to be monitored next and when (see Appendix 2). If the indication or use is off label for the product, the GP will be informed. The service user and/or carer will also have been informed, in accordance with Trust policy.
- The patient will receive supplies of antipsychotic from the hospital for a further two weeks from the date on the letter.
- Specialist services will review the patient as appropriate for the first 12 to 18 months of therapy thereafter.
- Alteration of (or advice about) antipsychotic dosage according to clinical parameters
- Evaluation of adverse events reported by the GP, and identification of any specific monitoring required.
- Restarting antipsychotic therapy should this be necessary.

GP Responsibilities

- Reply to the request for shared care as soon as practicable by faxing back the signed agreement at Annex 3.
- Monitoring the patient's overall health and well-being
- Specific monitoring agreed with the specialist; see Appendix 2.
- Prescribing antipsychotic
- Adverse drug reaction/Interaction monitoring
- Immediate referral to hospital is required if patients develop signs of Neuroleptic Malignant Syndrome (hyperthermia, muscle rigidity, autonomic instability, altered consciousness and elevated CPK levels)

Note: Neuroleptic Malignant Syndrome is an extremely rare adverse effect of all antipsychotics.

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

Contact	Speciality	Available	☎	Out of Hours
		Mon-Fri 8.30 – 5.00		

Appendix 1

Clinical background: People with LD constitute an extremely heterogeneous population. Mental illness, personality disorder and behavioural disorder requiring clinical intervention are overrepresented in people with a LD (Bernal and Hollins, 1995), possibly reflecting issues such as physical health co-morbidity (especially epilepsy), structural cerebral abnormality and genetic predisposition (O'Brien and Yule, 1995), and possibly an association with social deprivation and vulnerability (e.g. Flynn et al, 2002).
It is often possible to diagnose co-morbid psychiatric conditions using conventional criteria in people with milder degrees of LD. However, as a very rough rule, presentations become increasingly atypical as the level of disability increases (Bernal and Hollins, 1995). Schizophrenia, for example, is a diagnosis that can only reliably be made in those with mild LD who are able enough to communicate its key symptoms (Turner, 1989). As the severity of LD increases, clinicians become more inclined to consider clinical problems in diagnostic and descriptive ways, invoking the terms 'challenging behaviour' or 'problem behaviour'.

Antipsychotics have been used for behavioural problems in people with LD in the absence of mental illness for almost as long as they have been used for the treatment of schizophrenia, and despite their off-label status and thin evidence base in terms of masked, randomised controlled trials (Brylewski and Duggan, 1999), they have held an established place ever since, with older drugs giving way to newer ones over time.

Deb and colleagues (2006) have produced guidelines for the use of antipsychotics for behavioural indications in LD. Whilst the current evidence does not permit them to be prescriptive about treatment choice, the guidelines go some way to providing a framework for practice in terms of key domains such as assessment, capacity considerations, monitoring of effectiveness and adverse effects, communication and withdrawal. Specialist prescribers in the Trust will be utilising this framework, and compliance with the framework is subject to regular audit within the Trust.

References

Ahmed, Z., Fraser, W., Kerr, M.P. *et al* (2000) Reducing antipsychotic medication in people with a learning disability. *British Journal of Psychiatry,* 176, 42-46.

Aman, M.G., De Smedt, G., Derivan, A. *et al* (2002) Double-blind, placebo-controlled study of risperidone for the treatment of disruptive behaviours in children with subaverage intelligence. *American Journal of Psychiatry,* 159, 1337-1346.

Bernal, J. and Hollins, S. (1995) Psychiatric illness and learning disability: a dual diagnosis. *Advances in Psychiatric Treatment,* 1*,* 138-145.

Brylewski, J. and Duggan, L. (1999) Antipsychotic medication for challenging behaviour in people with intellectual disability: a systematic review of randomised control trials. *Journal of Intellectual Disability Research,* 43, 360-371.

Deb, S., Clarke, D. & Unwin, G. (2006) *Using medication to manage behaviour problems among adults with a learning disability.* University of Birmingham, UK.

Flynn, A., Matthews, H. and Hollins, S. (2002) Validity of the diagnosis of personality disorder in adults with learning disability and severe behavioural problems. *British Journal of Psychiatry,* 180, 543-546.

NICE schizophrenia guideline CG82 (updated March 2009) www.nice.org.uk/guidance/CG82

O'Brien, G. and Yule, W. (1995) *Behavioural Phenotypes.* Cambridge: McKeith Press.

Paton C., Barnes TRE., Cavanagh M-R., Taylor, D., on behalf of the POMH-UK project team. Use of antipsychotic medication in people with a learning disability. September 2009

Appendix 2 **Monitoring of patients taking atypical antipsychotics**

Atypical antipsychotics differ in their potential to cause the metabolic syndrome & diabetes: high risk antipsychotics include e.g. Olanzapine & Clozapine, intermediate risk antipsychotics include e.g. Quetiapine, and lower risk antipsychotics include e.g. Haloperidol, Aripiprazole, Ziprasidone, & Risperidone. 80% of patients developing Diabetes will do so in the first year of treatment. **The following represents minimum recommended monitoring requirements, clinicians may monitor more frequently if clinically indicated**

Time Period	Drug/ Class
	Antipsychotic
Prior to initiation = baseline	**All:** f- Glucose, f- Lipid (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides), U&Es, LFTs, pulse & BP, BMI, ECG (only if CV disease or at high risk) **Clozapine, Sertindole, Zotepine, Pimozide:** ECG **Clozapine:** for monitoring **during** initiation, refer to Clozapine Policy & Procedures
1 month	**Olanzapine, Clozapine:** f-Glucose, pulse & BP, BMI
3 months	All: f-Glucose, f-Lipid, BMI
6 months	BMI
9 months	BMI
12 months	All: f-Glucose, f-Lipids (>40 years), BP, BMI
Annually after first year	All: f-Glucose, f-Lipids (>40 years), pulse & BP, BMI Quetiapine: additionally TFTs
Additional testing requirement to annual	All- in children & adolescents: BMI 6-monthly

The following paraclinical tests may be indicated:

Prolactin	If patient has galactorhoea, menstrual abnormalities, increased breast growth, and/or changed libido. Routinely in children & adolescents at baseline before starting any medication
HbA1c Hemoglobin	If patient has clinically manifest Diabetes Mellitus – see NICE Guideline 66 for schedules
Clotting studies	If patients show excessive bruising
S-levels, U-drug screen, X-rays, EEG, MRI, CT, SPECT etc	If clinically indicated
All tests mentioned above need to be taken more often if a deterioration – either clinically or biochemically – is noted.	

Atypical Antipsychotic

Adverse Effects

Common adverse effects include sedation, movement problems, weight gain, anticholinergic side effects, blurred vision and sexual problems. For full details, see Summary of Product Characteristics for the individual drug.

Neuroleptic malignant syndrome (NMS) – hypothermia, muscle rigidity, autonomic instability, altered consciousness and elevated CPK levels- is an extremely rare adverse effect of all antipsychotics

Should a patient develop signs suggestive of neuroleptic malignant syndrome immediate referral to hospital is required and all antipsychotics should be discontinued immediately.

Side Effects	Action
• Tardive Dyskinesia	Refer to consultant A reduction in dose, discontinuation or change to an alternative (atypical) antipsychotic may be required
• Neuroleptic malignant syndrome (NMS)	Discontinue antipsychotic(s) Refer immediately to consultant
• Somnolence/Drowsiness	Restrict dose to night time only. Patients should be advised not to drive or operate machinery
• Constipation	Recommend a high fibre diet Consider adding a bulk-forming and/or stimulant laxative
• Dry mouth	Recommend chewing sugar-free gum
• Hypotension/dizziness	Advise patient to take time to get up. Measure b.p. periodically in patients over 65 years
• Weight gain	Encourage a healthy balanced diet and regular exercise
• Increase in prolactin levels (transient)	If symptoms of hyperprolactinaemia occur (rare) a reduction in dose may be required. Refer to consultant.

Ask about side effects at every consultation.

Annex 3

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

Shared Care Agreement for Risperidone, Olanzapine, Quetiapine, Aripiprazole, or Amisulpride for Behavioural indications in DNLD

Name of Prescriber:

Specialist Area:

Telephone Number:

Fax Number:……

Signature: Date:

Patient's Name:

Address:

Drug and dose:

Name of GP:

Signature: Date:

Practice Address