

Care Pathway for commencement of Clozapine within a community setting

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1. INTRODUCTION

Following the European harmonization of the Clozaril summary of product characteristics (SmPC) and parallel licensing of generic clozapine products, it is no longer a license requirement for a patient to be initiated on treatment within an in-patient environment

Out-patient initiation of clozapine will improve access of patients to an effective treatment. It will allow patients to be treated in an environment most appropriate for them. It is also likely to result in decreased waiting times for other patients for psychiatric hospital beds.

A Care Pathway can offer care that is efficient, effective and safe. This helps meet the standards highlighted in the national guidelines for the NHS. The Care Pathway will facilitate the commencement of clozapine therapy within a community setting as an alternative to admission to hospital. It aims to:

- Offer a safe and controlled environment in which current out-patient clients can begin clozapine therapy
- Enhance the continuity of care for a client group who may have long term involvement with the clozapine clinic.
- Reduce the pressure on in-patient facilities.

These patients will need a care coordinator who can be contacted in the event of missed appointments or other problems. The care-co-ordinator role is best undertaken by a community worker but can be a member of the medical team who may then delegate to their CMHT in emergencies

2. INSTRUCTIONS FOR USE

This Care Pathway will be the core document for all medical and nursing notes specific to this intervention. The Consultant Psychiatrist or deputy completes the referral and the acceptance checklist. The identified nurse is responsible for coordinating initial management one week before initiation of therapy.

On-going assessment is completed by the identified nurse at defined intervals. Any variance from the pathway and the expected outcomes must be recorded in the space provided. This allows scope to record anything not covered by the pathway. Its use should also be encouraged to record communication with the patient and where appropriate, their carer and family, in line with the Trust confidentiality policy.

3. STAFF ROLES

A member of the nursing staff will co-ordinate the process and liaise with the clozapine monitoring services as required. The identified nurse will also liaise with relevant disciplines about changes in the patient's mental and physical health and any adverse reactions to Clozapine.

Direct and indirect pharmaceutical support will be provided. Acute Trust pharmacy colleagues at site hospital will dispense the clozapine prescribed. and advice will be available from them on relevant management issues. For more clinically focused advice the chief pharmacist for mental health may be separately contacted.

Medical staff will review new patients at the clinic one week before commencing Clozapine therapy and a minimum of once a week for the period covered by the pathway. Further reviews will be arranged if required. Prescriptions will be completed by medical staff on a clozapine initiation card which is located at the back of the pack.

4. CRITERIA FOR COMMENCING CARE PATHWAY (SEE FORM 1) **All patients should fulfill the following criteria**

Have been given a diagnosis of treatment resistant schizophrenia and fall within the NICE guidelines which state that the patient should be:

non-responsive to two other neuroleptic medications (one of which should be an atypical) for a period of 6—8 weeks each at adequate dosage.

Have been given a full physical assessment by the prescribing doctor or a member of their team.

Have no contra-indications to treatment as described in relevant Clozapine Summary of Product Characteristics.

Have a carer or relative who is :

- Willing to stay with the patient during Clozapine initiation (including being at home with the patient at night and at weekends for the duration of the programme)
- Able to supervise the evening dose of medication for day 2 until the end of the programme
- Able to accompany the patient to and from the clinic for the duration of the programme

When this is not available, it may be possible to arrange for alternative support in advance but this will depend on available resources.

Be in direct contact with relevant professionals on daily basis during first two weeks of treatment, and weekly thereafter for blood monitoring.

Be fully aware of requirements of the treatment and of common side effects and their management.

A doctor from the prescribing team must be readily available by telephone during the two week initiation period to provide support to the team.

5. CONSENT TO TREATMENT

The patient's consultant and prescribing doctor must ensure that consent has been obtained and documented in line with Trust policy. They must be satisfied that the patient has given informed consent to commencing Clozapine. This process must include giving an explanation about the risks associated with starting Clozapine outside of an in-patient facility, balanced by the possible benefits of taking the drug. The patient and their carer(s) must be made aware that the product licence is contravened by starting treatment in the community.

Agreed documentation for recording consent is included in this care pathway.

6. EMERGENCIES / OUT OF HOURS PROBLEMS

When a patient presents with raised temperature, sore throat or other signs of infection it is important to check their white blood cell count as a precautionary measure. Prior agreement must be obtained from an identified acute psychiatry in-patient ward, for the patient to attend for a blood test if this situation arises out of hours. This is to be arranged with the appropriate modern matron. Further management guidelines are available in the company literature direct or from the manufacturer.

Emphasis must be given to patient and their carer / relatives not to panic. A blood sample must be taken at the in-patient ward and a local blood result obtained (24 hour service). If a red result is obtained Clozapine must be discontinued. Further management guidelines following a red result are given in the company literature.

If result is green then treat any signs of infection symptomatically (paracetamol to lower temp. etc)

In the event of a sudden deterioration in mental health (out of hours), the patient or carer / relative will contact identified acute ward for assessment by the on-call doctor.

7. GP'S

The patient's GP will be given a "pack" of information including the care coordination documentation, the name of the supervising nurse, the name of the RMO, the contact number for the mental health pharmacist and the company medicines information line. They will also receive the "Clozapine with Confidence" leaflet.

8. DNA PROCEDURE

If a patient fails to attend as arranged, the nurse will attempt to contact patient / carer. If this is not successful, the care coordinator and responsible doctor will be contacted to decide a course of action. If doses are missed for 48 hours a return to baseline titration is required.

9. SEIZURE

There is an accepted adverse risk of Grand Mal seizure during initiation of treatment with Clozapine (less than 10%). this can occur at any time and is dose dependent. Incidence rises at doses above 600mg/day

The possibility of a seizure at home, and action to be taken, must be discussed by the identified nurse, the patient and carer. Specific management plan for this possibility will depend on individual circumstances and will be agreed by the consultant psychiatrist or deputy prior to commence of the daily pathway.

In the event of a seizure provide first aid measures to promote patient safety and notify medical staff immediately. Further management guidelines following a seizure are available in company literature.

11. SPECIAL NOTES CONCERNING CARDIA SAFETY

(Clozapine and cardiac safety: updated advice for prescribers. Current Problems in Pharmacovigilance. p7: vol 28, October 2002)

A recent re-evaluation of serious cardiac events in association with the use of Clozapine has resulted in a strengthening of the warnings concerning myocardial disease in Clozapine users.

Before starting Clozapine therapy, patients are required to undergo a history and physical examination. Patients with a history of cardiac illness or abnormal cardiac findings on physical examination should be referred to a specialist for other examinations. These might include an ECG and echocardiogram, and Clozapine should only be initiated if severe heart disease is excluded and the benefits of treatment are considered to clearly outweigh the risks.

It is recommended that the prescribing doctor should consider performing a pre treatment ECG to allow comparisons if symptoms develop later.

Rare cases of fatal Myocarditis have been reports. The increased risk of this occurs most commonly in the first two months of treatment.

Tachycardia is a common side effect of Clozapine treatment that occurs in about 25% of users, especially during dose titration in early treatment. However, it is also a key symptom of myocardial disease.

It is therefore essential that patients who have persistent Tachycardia at rest, especially in the first two months of treatment, are closely monitored for other signs and symptoms of Cardiomyopathy.

These include palpitations, symptoms mimicking myocardial infarction, chest pain and other unexplained symptoms of heart failure.

If Clozapine-induced Myocarditis or Cardiomyopathy is suspected, treatment should be discontinued and an urgent referral made to a cardiologist. Patients who have developed these conditions should not be re-exposed to Clozapine.

TREATMENT PROGRAMME

The basic treatment programme is described in detail. The initial dose of Clozapine will be a single morning dose of 12.5mg. If tolerated, the Day 2 will be 12.5 mg b.d.

The dose titration given in the pathway is only a guide. After Day 2, dose should be titrated against side-effects, with the patient being maintained at the lowest effective dose.

Further guidance on all aspects of patient management is provided in the company literature.

COMMENCING CLOZAPINE THERAPY

A day by day pathway is supplied with this document for the first 16 days. This lists the tests and checks to be undertaken by the nurse. It covers:

- Arrival / departure times
- Frequency of observations
- Provision of a suitable environment
- Monitoring of side effects
- Contact with medical staff
- Contingency plans
- When to take blood samples
- When to order Clozapine
- Discharge from pathway

**CONSULTANT REFERRAL FOR
OUT PATIENT INITIATION OF CLOZAPINE**

| | | |
|---|-----------------|------------------|
| Last Name | First Name | Preferred Name |
| Address | Consultant | Care Coordinator |
| Tel No. | Tel No. | Tel No. |
| Date of Birth | Principal Carer | GP |
| Language of Choice | | |
| Date of Referral | | |
| NCRS No. | CPMS No. | |
| Reason for Referral to Service (include reasons why prescription was not initiated as an in-patient) | | |
| | | |
| Signed | | Date |

Patient's Name
 Consultant
 Clozapine registration No.

NCRS No.

ACCEPTANCE CHECKLIST

To be completed by doctor before programme begins

| Criteria | Signature / Date / Variance |
|--|--------------------------------|
| Patient fulfills standard product and Trust criteria for receiving Clozapine | |
| History has been taken and patient has been given a full physical assessment by the prescribing doctor or a member of their team. Patients with a history of cardiac illness or abnormal cardiac findings should be referred to a specialist (see sec. 11). | |
| The prescribing doctor should consider a pre-treatment ECG to allow future comparisons | |
| Contra-indications to treatment as described in Summary of Product Characteristics have been acknowledged. | |
| <p>Has a carer or relative who is :</p> <ul style="list-style-type: none"> • Willing to stay with the patient during Clozapine initiation (including being at home with the patient at night and at weekends for the duration of the programme) • Able to supervise the evening dose of medication from day 2 until the end of the programme • Able to accompany the patient to and from the clinic for the duration of the programme <p>When this support is not available, it may be possible to arrange for alternative support in advance, but this will depend on local resources at the time.</p> | |
| Patient able to attend a community facility on a daily basis during the first two weeks of treatment and weekly thereafter for blood monitoring. | |
| Requirements of treatment and of common side effects and their management have been discussed. | |
| A doctor from the prescribing team is readily available by telephone during the two week initiation period to provide support to the team. | <p>Name</p> <p>Contact No.</p> |
| The patient's consent has been obtained in line with Trust policy | |
| Copy of current care programme and relate risk assessment /CAN sent to Day Hospital. | |

Patient's Name
 Consultant
 Clozapine registration No.

NCRS No.

INITIAL MANAGEMENT
 (NURSE TO COORDINATE IN WEEK PRIOR TO COMMENCING TREATMENT
 ORDER SUPPLY BY WEDNESDAY)

Care Pathway

Complete Information as required and initial
 (more space on back of sheet)

| | | |
|---|----------------|------|
| Ensure that patients and their carers are fully about the process of commencing Clozapine therapy. Ensure that they have a copy of the "Clozapine with Confidence" leaflet and specific information about starting Clozapine at the day hospital. | | |
| Discuss the importance of not driving or traveling alone during weeks 1 and 2 because of possible drowsiness and small risk of collapse. | | |
| Discuss the possibility of seizure and actions to be taken in the event. | | |
| Ensure that notes have been received at Day Hospital | | |
| Register patient with Clozapine Patient Monitoring Service (CPMS) | | |
| Initial blood test completed and sent to CPMS | Date | Sign |
| Take baseline blood pressure, temperature, pulse and weight | Blood Pressure | |
| | Temperature | |
| | Pulse | |
| | Weight | |
| When a "green" result is received the patient is given a date to commence therapy (the initial result is valid for 14 days) | | |
| Clozapine is ordered from pharmacy ready for start date | | |
| Assess for optimum way of presenting medications (eg compliance aid) | | |
| Inform acute in-patients services manager of start date and provide with required information including CPA / risk assessment, dosing schedule, last clinic letter | | |
| Inform GP and care coordinator | | |
| Where appropriate, confirm with medical team that no other medical investigations are necessary | | |
| Arrange for patient to arrive at clinic by 9:00 on Monday morning | | |
| Book a room for the patient / carer available for the period covered by the pathway. Arrangements may be made for the patient to attend certain activity groups at the day hospital if the patient wishes. | | |

Patient's Name
Consultant
Clozapine registration No.

NCRS No.

INITIAL MANAGEMENT
(TO BE COMPLETED ONE WEEK PRIOR TO COMMENCING TREATMENT)

DATE

Variance from pathway and action taken / comments. Must be signed.

Patient's Name
 Consultant
 Clozapine registration No.

NCRS No.

CLOZAPINE INITIATION CARD

| | | | |
|-----------|---------------|------------|----------------|
| Last Name | First Name | NCRS No. | Community Base |
| CPMS No | Date of Birth | Consultant | Code |

SPECIAL INSTRUCTIONS Unless otherwise stated please supply in a box with instructions to *“Take as directed on the dosage guide supplied by the clinic”*

| Dose | Clozapine AM | Clozapine PM | Pack Description | Contents | Prescriber's Signature |
|--------|--------------|--------------|------------------|------------------------|------------------------|
| Day 1 | 12.5mg | None | A | 7 x 25mg | |
| Day 2 | 12.5mg | 12.5mg | | | |
| Day 3 | 12.5mg | 25mg | | | |
| Day 4 | 25mg | 25mg | | | |
| Day 5 | 25mg | 50mg | B | 7 x 100mg 28 x 25mg | |
| Day 6 | 14mg | 75mg | | | |
| Day 7 | 25mg | 75mg | | | |
| Day 8 | 50mg | 75mg | | | |
| Day 9 | 50mg | 100mg | | | |
| Day 10 | 50mg | 100mg | | | |
| Day 11 | 50mg | 125mg | | | |
| Day 12 | 100mg | 100mg | C | 21 x 100mg 7 x 25mg | |
| Day 13 | 100mg | 125mg | | | |
| Day 14 | 100mg | 150mg | | | |
| Day 15 | 100mg | 175mg | | | |
| Day 16 | 100mg | 200mg | | | |
| Day 17 | 100mg | 200mg | | | |
| Day 18 | 100mg | 200mg | Use | Community | Card |

DISPENSING AND ISSUING RECORD

| | | | | |
|-------------------|---|---|---|-------|
| Dispensing date | | | | |
| CPSM Blood Status | | | | |
| Released by | | | | |
| Pack Issued | A | B | C | Other |
| Dispensed by | | | | |
| Date issued | | | | |
| Given by | | | | |

Where can I get further information ?

If you wish to know more about Clozapine as a treatment, please speak to your prescribing doctor or support worker. The specialist Mental Health Pharmacist can also be asked to come and answer your questions. There are other information sheets available on Clozapine.

If you would like to know more about schizophrenia and perhaps meet others who are in similar circumstances, then the addresses below may be of some help to you.

Rethink

**28 Castle Street
Kingston upon Thames
Surrey
KT1 2SS**

**Tel: 0208 547 3937 (administration)
0208 974 6814 (Advice 10am - 3pm)**

SANE

**199 - 205 Old Marleybone Rode
London
NW1 5QP**

**Tel: 0207 724 6520 (Administration)
0845 678 000 (Helpline 2pm - midnight)**

MIND

**15 - 19 Broadway
London
E15 4BQ**

Tel: 0208 519 2122

If you need to see another doctor or go to hospital, please take this card with you. This will help to ensure that you get the best treatment from these services.

Starting Clozapine Dosage Guide

Clozapine is used when other antipsychotics have not helped

Clozapine consistently achieves better results than other antipsychotics

Commitment to clozapine involves having regular blood tests

No blood - no drug
This is for your own safety

Many people who take clozapine are able to achieve much more

Getting the best from your
clozapine medication

WORCESTERSHIRE MENTAL HEALTH PARTNERSHIP NHS TRUST

| | | | |
|----------------------------|---------------|-------------|------------|
| Surname | Forename | Clinic Base | |
| Clozapine Registration no. | Date of Birth | Address | Consultant |

CLOZARIL (CLOZAPINE) DOSING CARD

| Date | Day | Clozapine Dosage | | Notes |
|------|-----------|------------------|------------------------|--------------------------------------|
| | | Breakfast | Bedtime | Make your own notes in second column |
| | Monday | Half a 25mg | None | Receive first supply |
| | Tuesday | Half a 25mg | Half a 25mg | Blood test |
| | Wednesday | Half a 25mg | One 25mg | |
| | Thursday | One 25mg | One 25mg | |
| | Friday | One 25mg | Two 25mg | Receive second supply |
| | Saturday | One 25mg | Three 25mg | |
| | Sunday | One 25mg | Three 25mg | |
| | Monday | Two 25mg | Three 25mg | |
| | Tuesday | Two 25mg | One 100mg | Blood Test |
| | Wednesday | Two 25mg | One 100mg | |
| | Thursday | Two 25mg | One 25mg + one 100mg | |
| | Friday | Two 25mg | One 100mg | Receive third supply |
| | Saturday | One 100mg | One 25mg + one 100mg | |
| | Sunday | One 100mg | Two 25mg + one 100mg | |
| | Monday | One 100mg | Three 25mg + one 200mg | |
| | Tuesday | One 100mg | Two 100mg | Blood Test |
| | Wednesday | One 100mg | Two 100mg | |
| | Thursday | One 100mg | Two 100mg | |

| | |
|----------------------------|----------|
| Patient's Name | NCRS No. |
| Consultant | |
| Clozapine registration No. | |

DAILY PATHWAY

DAY ONE (Monday)
CARE PATHWAY

Date _____
Nurse to complete information as required and initial

| | | | | | | |
|--|----------------|-------|-------|-------|-------|-------|
| Ensure that patient has somewhere to sit or lie quietly should they need to | | | | | | |
| Patient arrives at clinic for 09:00 | | | | | | |
| Assess understanding of process with patient and provide further information required. Check that general health has not deteriorated since initial management | | | | | | |
| Give first dose (12.5mg) of Clozapine | Dosage | Time | | | | |
| Monitor and record temperature, pulse and blood pressure on arrival, then 2 hourly and then prior to leaving at 16:30. In event of abnormal results follow company advice. | | 09:00 | 11:00 | 13:00 | 15:00 | 16:30 |
| | Temp | | | | | |
| | Pulse | | | | | |
| | Blood Pressure | | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation and tachycardia. | | | | | | |
| Notify medical staff of any significant change in condition of patient. | | | | | | |
| Advise to ring acute ward (out of hours) in event of raised temperature, sore throat or other signs of infection. | | | | | | |
| The patient can be allowed home (with agreed escort) from 16:30 to return at 9:00 the following day. Driving is not advised at this point. | | | | | | |
| Variance from pathway and action taken / comments | | | | | | |
| | | | | | | |

| | |
|--|----------|
| Patient's Name Consultant Clozapine registration No. | NCRS No. |
|--|----------|

DAILY PATHWAY

DAY TWO
CARE PATHWAY

Date _____
Nurse to complete information as required and initial

| | | | | | | |
|--|----------------|-------|-------|-------|--|--|
| Ensure that patient has somewhere to sit or lie quietly should they need to | | | | | | |
| Patient arrives at clinic for 09:00 | | | | | | |
| Assess understanding of process and provide further information required. | | | | | | |
| Give second dose (12.5mg) of Clozapine | Dosage | Time | | | | |
| Monitor and record temperature, pulse and blood pressure on arrival, then 3 hourly. In event of abnormal results follow company advice. | | 09:00 | 12:00 | 15:00 | | |
| | Temp | | | | | |
| | Pulse | | | | | |
| | Blood Pressure | | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation, tachycardia and constipation. | | | | | | |
| Notify medical staff of change in condition of patient of patient and arrange for patient to be seen if needed. | | | | | | |
| Take "first blood on treatment" and send to laboratory | | | | | | |
| Supply to patient their evening dose of medication for Day 2. it may be appropriate, following assessment, to give supply of medication for rest of week a this point. | | | | | | |
| Instruct patient / carer that evening dose is to be taken at 18:00. | | | | | | |
| Advise to ring acute ward in event of raised temperature, sore throat or other signs of infection (out of hours only) | | | | | | |
| The patient can be allowed home (with agreed escort) from 15:00 to return at 09:00 the following day. Driving is not advised at this point. | | | | | | |
| Variance from pathway and action taken / comments | | | | | | |
| | | | | | | |

Patient's Name
 Consultant
 Clozapine registration No.

NCRS No.

DAILY PATHWAY

DAY THREE
 CARE PATHWAY

Date _____
 Nurse to complete information as required and initial

| | | | | | | |
|---|----------------|-------|-------|-------|--|--|
| Ensure that patient has somewhere to sit or lie quietly should they need to | | | | | | |
| Patient arrives at clinic for 09:00 | | | | | | |
| Check with patient that evening dose was taken correctly. | | | | | | |
| Give morning dose of Clozapine | Dosage | Time | | | | |
| Monitor and record temperature, pulse and blood pressure on arrival, then 3. In event of abnormal results follow company advice. | | 09:00 | 12:00 | 15:00 | | |
| | Temp | | | | | |
| | Pulse | | | | | |
| | Blood Pressure | | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation, tachycardia and constipation. | | | | | | |
| Notify medical staff of any significant change in condition of patient and arrange for patient to be seen if needed. | | | | | | |
| If not already given, supply patient their evening dose of medication for Day 3. Instruct patient / carer that evening dose is to be taken at 18:00 | | | | | | |
| Request prescription for further supply of Clozapine from medical team and send to pharmacy for delivery on Friday pending a "green" result. | | | | | | |
| Advise to ring acute ward in event of raised temperature, sore throat or other signs of infection (out of hours only) | | | | | | |
| The patient can be allowed home (with agreed escort) from 15:00 to return at 09:00 the following day. Driving is not advised at this point | | | | | | |
| Variance from pathway and action taken / comments | | | | | | |

| | |
|----------------------------|----------|
| Patient's Name | NCRS No. |
| Consultant | |
| Clozapine registration No. | |

DAILY PATHWAY

DAY FOUR
CARE PATHWAY

Date _____
Nurse to complete information as required and initial

| | | | | | | |
|---|----------------|-------|-------|--|--|--|
| Ensure that patient has somewhere to sit or lie quietly should they need to | | | | | | |
| Patient arrives at clinic for 09:00 | | | | | | |
| Check with patient that evening dose was taken correctly. | | | | | | |
| Give morning dose of Clozapine | Dosage | Time | | | | |
| Monitor and record temperature, pulse and blood pressure on arrival, then at 14:00. In event of abnormal results follow company advice. | | 09:00 | 14:00 | | | |
| | Temp | | | | | |
| | Pulse | | | | | |
| | Blood Pressure | | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation, tachycardia and constipation. | | | | | | |
| Notify medical staff of any significant change in condition of patient and arrange for patient to be seen if needed. | | | | | | |
| If not already given, supply patient their evening dose of medication for Day 4. Instruct patient / carer that evening dose is to be taken at 18:00 | | | | | | |
| Request prescription for further supply of Clozapine from medical team and send to pharmacy for delivery on Friday pending a "green" result. | | | | | | |
| Advise to ring acute ward in event of raised temperature, sore throat or other signs of infection (out of hours only) | | | | | | |
| The patient can be allowed home (with agreed escort) from 15:00 to return at 09:00 the following day. Driving is not advised at this point | | | | | | |
| Variance from pathway and action taken / comments | | | | | | |
| | | | | | | |

Patient's Name
 Consultant
 Clozapine registration No.

NCRS No.

DAILY PATHWAY

DAY FIVE
 CARE PATHWAY

Date _____
 Nurse to complete information as required and initial

| | | | | | |
|--|----------------|-------|-------|--|--|
| Ensure that patient has somewhere to sit or lie quietly should they need to | | | | | |
| Patient arrives at clinic for 09:00 | | | | | |
| Check with patient that evening dose was taken correctly. | | | | | |
| Give morning dose of Clozapine | Dosage | Time | | | |
| Monitor and record temperature, pulse and blood pressure on arrival, then at 14:00. In event of abnormal results follow company advice. | | 09:00 | 14:00 | | |
| | Temp | | | | |
| | Pulse | | | | |
| | Blood Pressure | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation, tachycardia and constipation. | | | | | |
| Notify medical staff of any significant change in condition of patient and arrange for patient to be seen if needed. | | | | | |
| If not already supplied, supply patient doses of clozapine to last from evening dose for Day 5 morning dose for Day 8. | | | | | |
| Advise to ring acute ward in event of raised temperature, sore throat or other signs of infection (out of hours only) | | | | | |
| The patient can be allowed home (with agreed escort) from 15:00 to return at 09:00 the following day. Driving is not advised at this point | | | | | |
| Variance from pathway and action taken / comments | | | | | |

Patient's Name
 Consultant
 Clozapine registration No.

NCRS No.

DAILY PATHWAY

DAY EIGHT
 CARE PATHWAY

Date _____
 Nurse to complete information as required and initial

| | | | | | |
|--|----------------|-------|-------|--|--|
| Ensure that patient has somewhere to sit or lie quietly should they need to | | | | | |
| Patient arrives at clinic for 09:00 | | | | | |
| Check with patient that weekend medication was taken correctly and without incident | | | | | |
| Give morning dose of Clozapine | Dosage | Time | | | |
| Monitor and record temperature, pulse and blood pressure on arrival, then at 14:00. In event of abnormal results follow company advice. | | 09:00 | 14:00 | | |
| | Temp | | | | |
| | Pulse | | | | |
| | Blood Pressure | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation, tachycardia and constipation. | | | | | |
| Notify medical staff of any significant change in condition of patient and arrange for patient to be seen if needed. | | | | | |
| If not already given, give patient evening dose of Clozapine for Day 8 | | | | | |
| Advise to ring acute ward in event of raised temperature, sore throat or other signs of infection (out of hours only) | | | | | |
| The patient can be allowed home (with agreed escort) from 14:00 to return at 09:00 the following day. Driving is not advised at this point | | | | | |
| Variance from pathway and action taken / comments | | | | | |

| | |
|----------------------------|----------|
| Patient's Name | NCRS No. |
| Consultant | |
| Clozapine registration No. | |

DAILY PATHWAY

DAY NINE
CARE PATHWAY

Date _____
Nurse to complete information as required and initial

| | | | | | | |
|--|----------------|-------|-------|--|--|--|
| Ensure that patient has somewhere to sit or lie quietly should they need to | | | | | | |
| Patient arrives at clinic for 09:00 | | | | | | |
| Check with patient that evening medication was taken correctly and without incident | | | | | | |
| Give morning dose of Clozapine | Dosage | Time | | | | |
| Monitor and record temperature, pulse and blood pressure on arrival, then at 14:00. In event of abnormal results follow company advice. | | 09:00 | 14:00 | | | |
| | Temp | | | | | |
| | Pulse | | | | | |
| | Blood Pressure | | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation, tachycardia and constipation. | | | | | | |
| Notify medical staff of any significant change in condition of patient and arrange for patient to be seen if needed. | | | | | | |
| Take blood sample and send to laboratory | | | | | | |
| If not already given, give patient evening dose of Clozapine for Day 9 | | | | | | |
| Advise to ring acute ward in event of raised temperature, sore throat or other signs of infection (out of hours only) | | | | | | |
| The patient can be allowed home (with agreed escort) from 14:00 to return at 09:00 the following day. Driving is not advised at this point | | | | | | |

Variance from pathway and action taken / comments

| | |
|----------------------------|----------|
| Patient's Name | NCRS No. |
| Consultant | |
| Clozapine registration No. | |

DAILY PATHWAY

DAY TEN
CARE PATHWAY

Date _____
Nurse to complete information as required and initial

| | | | | | |
|--|----------------|-------|-------|--|--|
| Ensure that patient has somewhere to sit or lie quietly should they need to | | | | | |
| Patient arrives at clinic for 09:00 | | | | | |
| Check with patient that evening medication was taken correctly and without incident | | | | | |
| Give morning dose of Clozapine | Dosage | Time | | | |
| Monitor and record temperature, pulse and blood pressure on arrival, then at 14:00. In event of abnormal results follow company advice. | | 09:00 | 14:00 | | |
| | Temp | | | | |
| | Pulse | | | | |
| | Blood Pressure | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation, tachycardia and constipation. | | | | | |
| Request prescription for further supply of Clozapine from medical team and send to pharmacy for delivery on Friday, pending a "green" result | | | | | |
| Notify medical staff of any significant change in condition of patient and arrange for patient to be seen if needed. | | | | | |
| If not already given, give patient evening dose of Clozapine for Day 10 | | | | | |
| Advise to ring acute ward in event of raised temperature, sore throat or other signs of infection (out of hours only) | | | | | |
| The patient can be allowed home (with agreed escort) from 14:00 to return at 09:00 the following day. Driving is not advised at this point | | | | | |

Variance from pathway and action taken / comments

Patient's Name
 Consultant
 Clozapine registration No.

NCRS No.

DAILY PATHWAY

DAY ELEVEN
 CARE PATHWAY

Date _____
 Nurse to complete information as required and initial

| | | | | | |
|--|----------------|-------|-------|--|--|
| Ensure that patient has somewhere to sit or lie quietly should they need to | | | | | |
| Patient arrives at clinic for 09:00 | | | | | |
| Check with patient that evening medication was taken correctly and without incident | | | | | |
| Give morning dose of Clozapine | Dosage | Time | | | |
| Monitor and record temperature, pulse and blood pressure on arrival, then at 14:00. In event of abnormal results follow company advice. | | 09:00 | 14:00 | | |
| | Temp | | | | |
| | Pulse | | | | |
| | Blood Pressure | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation, tachycardia and constipation. | | | | | |
| Notify medical staff of any significant change in condition of patient and arrange for patient to be seen if needed. | | | | | |
| If not already given, give patient evening dose of Clozapine for Day 11 | | | | | |
| Advise to ring acute ward in event of raised temperature, sore throat or other signs of infection (out of hours only) | | | | | |
| The patient can be allowed home (with agreed escort) from 14:00 to return at 09:00 the following day. Driving is not advised at this point | | | | | |
| Variance from pathway and action taken / comments | | | | | |

Patient's Name
 Consultant
 Clozapine registration No.

NCRS No.

DAILY PATHWAY

DAY TWELVE
 CARE PATHWAY

Date _____
 Nurse to complete information as required and initial

| | | | | | |
|--|----------------|-------|-------|--|--|
| Ensure that patient has somewhere to sit or lie quietly should they need to | | | | | |
| Patient arrives at clinic for 09:00 | | | | | |
| Check with patient that evening medication was taken correctly and without incident | | | | | |
| Give morning dose of Clozapine | Dosage | Time | | | |
| Monitor and record temperature, pulse and blood pressure on arrival, then at 14:00. In event of abnormal results follow company advice. | | 09:00 | 14:00 | | |
| | Temp | | | | |
| | Pulse | | | | |
| | Blood Pressure | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation, tachycardia and constipation. | | | | | |
| Notify medical staff of any significant change in condition of patient and arrange for patient to be seen if needed. | | | | | |
| If not already given, give patient evening dose of Clozapine for Day 12 to morning dose for Day 16 | | | | | |
| Advise to ring acute ward in event of raised temperature, sore throat or other signs of infection (out of hours only) | | | | | |
| The patient can be allowed home (with agreed escort) from 14:00 to return at 09:00 the following day. Driving is not advised at this point | | | | | |
| Variance from pathway and action taken / comments | | | | | |

| | |
|----------------------------|----------|
| Patient's Name | NCRS No. |
| Consultant | |
| Clozapine registration No. | |

DAILY PATHWAY

DAY FIFTEEN
CARE PATHWAY

Date _____
Nurse to complete information as required and initial

| | |
|--|--|
| Ring client to establish that they have taken their medication correctly and without incident. | |
| Establish if side effects present | |
| Remind to attend Clozapine clinic the following day at 11:00 for blood test and review | |

Variance from pathway and action taken / comments

| | |
|----------------------------|----------|
| Patient's Name | NCRS No. |
| Consultant | |
| Clozapine registration No. | |

DAILY PATHWAY

DAY SIXTEEN
CARE PATHWAY

Date _____
Nurse to complete information as required and initial

| | | | | | |
|--|----------------|-------|-------|--|--|
| Patient arrives at clinic at 11:00 | | | | | |
| Check with patient that they have taken their tablets correctly and without incident. | | | | | |
| Monitor and record temperature, pulse and blood pressure. In event of abnormal results follow company advice. | Dosage | Time | | | |
| | | 09:00 | 14:00 | | |
| | Temp | | | | |
| | Pulse | | | | |
| | Blood Pressure | | | | |
| Monitor patient for side effects including drowsiness / sedation, hyper-salivation, tachycardia and constipation. | | | | | |
| Ensure patient is seen by medical staff who will decide on further titration and monitoring. | | | | | |
| Give routine blood test and send to laboratory in usual manner | | | | | |
| Request prescription for further supply of Clozapine and send to pharmacy for dispensing on receipt of satisfactory results. | | | | | |
| Give patient prescribed doses covered by green result. Arrange appointment for medication to be collected later in the week. | | | | | |
| Request patient to return the following Tuesday for blood test and review. | | | | | |
| Ensure that care coordinator is fully aware of progress. | | | | | |

Variance from pathway and action taken / comments

Patient's Name
Consultant
Clozapine registration No.

NCRS No.

DISCHARGE PROCEDURE

CARE PATHWAY

Date

Nurse to complete information as required and initial

| | |
|---|--|
| Patient discharged from care pathway to become Clozapine clinic patient | |
| Patient and carer / relative informed of follow up arrangements | |
| Prescription transferred to community / day patient card | |
| Record made in medical and nursing notes | |
| Summary sent to consultant | |
| Blood tests will continue according to the requirement of CPMS. Further increases in dosage will be made in the usual manner by the RMO | |
| Variance from pathway and action taken / comments | |

CONSENT FORM 1

Worcestershire Mental Health Partnership NHS Trust

Patient agreement to investigation or treatment

| Patient Details | | |
|----------------------|------|--------|
| Last Name : | | |
| First Name : | | |
| Date of Birth : | | |
| Language of Choice : | | |
| NCRS Number : | | |
| Gender : | Male | Female |

| Responsible health professional details | |
|---|--|
| Name : | |
| Job Title : | |

To be retained in patient's notes

| | | |
|-------------|-----------------|----------|
| Last Name : | Date of Birth : | NCRS No. |
|-------------|-----------------|----------|

Name of proposed procedure or course of treatment
Including brief explanation if medical term not clear

Statement of health professional
To be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the consent policy

I have explained the procedure to the patient. In particular I have explained:

The intended benefits:

Serious or frequent occurring adverse risks:

Any extra procedures which may become necessary during the procedure

Blood transfusion
Other procedures (please specify)

I have also discussed what the procedure is likely to involve, the benefits and adverse risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet / tape has been provided:

This procedure will involve :

General and / or regional anesthesia local anesthesia sedation

| | | | |
|--------|--|------|--|
| Signed | | Date | |
|--------|--|------|--|

| | | | |
|--------------|--|-----------|--|
| Name (Print) | | Job Title | |
|--------------|--|-----------|--|

(Contact details (if patient wishes to discuss options later))

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand

| | | | |
|--------|--|------|--|
| Signed | | Date | |
|--------|--|------|--|

| | | | |
|--------------|--|--|--|
| Name (Print) | | | |
|--------------|--|--|--|

Top copy accepted by patient ? Yes No

Please tick

| | | |
|-------------|-----------------|----------|
| Last Name : | Date of Birth : | NCRS No. |
|-------------|-----------------|----------|

Statement of Patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2, which describes the benefits and adverse risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

| | | | |
|-----------------------|--|--------|--|
| Patient's Signature : | | Date : | |
|-----------------------|--|--------|--|

| | |
|--------------|--|
| Name (print) | |
|--------------|--|

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people / children may also like a parent to sign here (see notes)

| | | | |
|----------------------|--|--------|--|
| Parent's Signature : | | Date : | |
|----------------------|--|--------|--|

| | |
|--------------|--|
| Name (print) | |
|--------------|--|

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team testing the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

| | | | |
|--------|--|------|--|
| Signed | | Date | |
|--------|--|------|--|

| | | | |
|--------------|--|-----------|--|
| Name (Print) | | Job Title | |
|--------------|--|-----------|--|

Important Notes:

See also advance directive / living will (e.g. Jehovah's Witness form) tick if applicable

Patient has withdrawn consent (ask patient to sign / date here

Guidance to health professionals (to be read in conjunction with consent policy)

What a consent form is for

This form documents the patient's agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an *aide-memoir* to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face to face discussion with the patient.

The law on consent

See the Department of Health's reference guide to consent for examination or treatment for a comprehensive summary of the law on consent (also available at www.dh.gov.uk)

Who can give consent

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed". Then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17 and legally "competent" younger children, may therefore sign this form for themselves, but may like a parent to counter sign as well. If the child is not able to give consent for him or herself, someone with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for him or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asked you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given orally or non-verbally.

When NOT to use this form

If the patient is 18 or over and is not legally competent to give consent, you should use form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:

- They are unable to comprehend and retain information material to the decision and / or
- They are unable to weigh and use this information in coming to a decision

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives **cannot** be asked to sign this form on behalf of an adult who is not legally competent to consent for him or herself.

Information

Information about what the treatment will involve, its benefits and adverse risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated patients should be told about "significant adverse risks, which would affect the judgement of a reasonable patient". "Significant" has not been legally defined, but the GMC requires doctors to tell patients about "serious or frequently occurring" adverse effects. In addition if patients make clear they have particular concerns about certain kinds of adverse risk, you should make sure they are informed about these, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on page 2 of the form or in the patient's notes.

CONSENT FORM 2

Worcestershire Mental Health Partnership NHS Trust

Parental agreement to investigation or treatment for a child or young person

| Patient Details | | | |
|----------------------|------|--------|--|
| Last Name : | | | |
| First Name : | | | |
| Date of Birth : | | Age: | |
| Language of Choice : | | | |
| NCRS Number : | | | |
| Gender : | Male | Female | |

| Responsible health professional details | |
|---|--|
| Name : | |
| Job Title : | |

To be retained in patient's notes

| | | | |
|---|-----------------|-----------|--|
| Last Name : | Date of Birth : | NCRS No. | |
| Name of proposed procedure or course of treatment Including brief explanation if medical term is not clear | | | |
| Statement of health professional To be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the consent policy I have explained the procedure to the child and his or her parent(s). In particular I have explained : The intended benefits: | | | |
| Serious or frequent occurring adverse risks: | | | |
| Any extra procedures which may become necessary during the procedure Blood transfusion Other procedure (please specify | | | |
| I have also discussed what the procedure is likely to involve, the benefits and adverse risks of any available alternative treatments (including no treatment) and any particular concerns of this patient and his or her parents. | | | |
| The following leaflet / tape has been provided | | | |
| This procedure will involve : <div style="display: flex; justify-content: space-around;"> General and / or regional anesthesia local anesthesia sedation </div> | | | |
| Signed | | Date | |
| Name (Print) | | Job Title | |
| (Contact details (if child / parent wishes to discuss options later) | | | |
| Statement of interpreter (where appropriate) | | | |
| I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand | | | |
| Signed | | Date | |
| Name (Print) | | | |

Top copy accepted by patient ? Yes No

Please tick

| | | |
|-------------|-----------------|----------|
| Last Name : | Date of Birth : | NCRS No. |
|-------------|-----------------|----------|

Statement of Parent

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2, which describes the benefits and adverse risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask - we are here to help you and your child. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form and I confirm that I have parental responsibility for this child

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that my child will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to children having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save the life of my child or to prevent serious harm to his / her health.

I have been told about additional procedures which may become necessary during my child's treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

| | | | |
|-----------------------|--|-----------------------|--|
| Patient's Signature : | | Date : | |
| Name (print) | | Relationship to child | |

Child's agreement to treatment (if child wishes to sign)

I agree to have the treatment I have been told about.

| | | | |
|---------------------|--|--------|--|
| Child's Signature : | | Date : | |
| Name (print) | | | |

Confirmation of consent (to be completed by a health professional when the child is admitted for the procedure, if the parent / child has signed the form in advance)

On behalf of the team testing the patient, I have confirmed with the child and his or her parents that they have no further questions and wishes the procedure to go ahead.

| | | | |
|--------------|--|-----------|--|
| Signed | | Date | |
| Name (Print) | | Job Title | |

Important Notes:

See also advance directive / living will (e.g. Jehovah's Witness form) tick if applicable

Patient has withdrawn consent (ask patient to sign / date here)

Guidance to health professionals (to be read in conjunction with consent policy)

This form

This form should be used to document consent to a child's treatment, where that consent is being given by a person with parental responsibility for the child. The term "parent" has been used in this form as a shorthand for "person with parental responsibility". Where the children are legally competent to consent for themselves (see below), they may sign the standard "adult" consent form (form 1). There is space on that form for a parent to countersign if a competent child wishes them to do so.

Who can give consent

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. The courts have stated that if a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed" then he or she will be competent to give consent for himself or herself. If children are not able to give consent for themselves, someone with parental responsibility may do so on their behalf.

Although children acquire rights to give consent for themselves as they grow older, people with "parental responsibility" for a child retain the right to give consent on the child's behalf until the child reaches the age of 18. Therefore, for a number of years, both the child and a person with parental responsibility have the right to consent to the child's treatment. In law, health professionals only need the consent of one appropriate person before providing treatment. This means that in theory, it is lawful to provide treatment to a child under 18, which a person with parental responsibility has authorised, even if the child refuses. As a matter of good practice, however, you should always seek a competent child's consent before providing treatment unless any delay involved in doing so would put the child's life or health at adverse risk. Younger children should also be as involved as possible in decisions about their healthcare. Further advice is given in the Department's guidance *Seeking consent: working with children*. Any differences of opinion between the child and their parents, or between parents, should be clearly documented in the patient's notes.

Parental responsibility

The person(s) with parental responsibility will usually, but not invariably, be the child's birth parents. People with parental responsibility for a child include, the child's mother, the child's father if married to the mother at the child's conception, birth or later; a legally appointed guardian; the local authority if the child is on a care order; or a person named in a residence order in respect of the child. Fathers who have never been married to the child's mother will only have parental responsibility if they have acquired it through a court order or parental responsibility agreement (although this may change in the future)

Information

Information about what the treatment will involve, its benefits and adverse risks (including side effects and complications) and the alternatives to the particular procedure proposed, is crucial for children and their parents when making up their minds about treatment. The courts have stated that patients should be told about "significant adverse risks, which would affect the judgement of a reasonable patient". "Significant" has not been legally defined but the GMC required doctors to tell patients about "serious or frequently occurring" adverse risks. In addition, if patients make clear they have particular concerns about certain kinds of adverse risk, you should make sure they are informed about these, even if they are very small or rare. You should always answer questions honestly.

Guidance on law

See the Department of Health publications *Reference guide to consent for examination or treatment* and *Seeking consent: working with children* for a comprehensive summary of the law on consent (also available at www.dh.gov.uk/consent)

| | | |
|---|-----------------|-----------|
| Last Name : | Date of Birth : | NCRS No. |
| <p>Patient / parental agreement to investigate or treatment (procedures where consciousness not impaired)</p> <p>Name of procedure (include brief explanation if medical term not clear)</p> | | |
| <p>Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)</p> <p>I have explained the procedure to the patient / parent. In particular I have explained: The intended</p> <p>Serious or frequently occurring adverse risks</p> <p>I have also discussed what the procedure is likely to involve, the benefits and adverse risks of any available alternative treatment (including no treatment) and any particular concerns of those involved)</p> <p>The following leaflet / tape has been provided</p> | | |
| Signed | | Date |
| Name (Print) | | Job Title |
| <p>Statement of interpreter (where appropriate) I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand</p> | | |
| Signed | Name (Print) | Date |
| <p>Statement of patient / person with parental responsibility for patient</p> <ul style="list-style-type: none"> • I agree to the procedure described above • I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience. • I understand that the procedure will / will not involve local anaesthesia | | |
| Signed | | Date |
| Name (Print) | | Job Title |
| <p>Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient / parent has signed the form in advance) I have confirmed that the patient / parent has no further questions and wishes to the procedure to go ahead.</p> | | |
| Signed | | Date |
| Name (Print) | | Job Title |

Top copy accepted by patient ? Yes No

Please tick

Guidance to health professionals (to be read in conjunction with consent policy)

This Form

This form documents the patient's agreement (or that of a person with parental responsibility for the patient) to go ahead with the investigation or treatment that you have proposed. **It is only designed for procedures where the patient is expected to remain alert throughout and where an anaesthetist is not involved in their care, for example for drug therapy where written consent is deemed appropriate.** In other circumstances you should use either Consent Form 1 (for adults/competent children) or Consent Form 2 (parental consent for children/young people) as appropriate. Consent forms are not legal waivers – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients also have every right to change their mind after signing the form.

Who can give consent

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has “sufficient understanding and intelligence to enable him or her to understand fully what is proposed”, then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally “competent” younger children, may therefore sign this form for themselves, if they wish. If the child is not able to give consent for himself or herself, someone with parental responsibility may do so on their behalf. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete the form as usual and ask an independent witness to confirm that the patient has given consent orally or non verbally.

When NOT to use this form(see also “This form” above)

If the patient is 18 or over and is not legally competent to give consent, you should use Consent Form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:

- they are unable to comprehend and retain information material to the decision and / or
- they are unable to weigh and use this information in coming to a decision

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives **cannot** be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

Information

Information about what the treatment will involve, its benefits and adverse risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds about treatment. The courts have stated that patients should be told about “significant adverse risks which would affect the judgement of a reasonable patient”. “Significant” has not been legally defined, but the GMC requires doctors to tell patients about “serious or frequently occurring” adverse risks. In addition if patients make clear they have particular concerns about certain kinds of adverse risk, you should make sure they are informed about these, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patients receives at least very basic information about what is proposed. Where information is refused, you should document this overleaf or in the patient's notes.

The law on consent

See the Department of Health publications *Reference guide to consent for examination or treatment* for a comprehensive summary of the law on consent (also available at www.dh.gov.uk/consent)

CONSENT FORM 4

Worcestershire Mental Health Partnership NHS Trust

Form for adults who are unable to consent to investigation or treatment

| Patient Details | | | |
|----------------------|------|--------|--|
| Last Name : | | | |
| First Name : | | | |
| Date of Birth : | | Age: | |
| Language of Choice : | | | |
| NCRS Number : | | | |
| Gender : | Male | Female | |

| Responsible health professional details | |
|---|--|
| Name : | |
| Job Title : | |

To be retained in patient's notes

| | | |
|-------------|-----------------|----------|
| Last Name : | Date of Birth : | NCRS No. |
|-------------|-----------------|----------|

ALL SECTIONS TO BE COMPLETED BY HEALTH PROFESSIONAL PROPOSING THE PROCEDURE

A. Details of procedure or course of treatment proposed

(see guidance to health professionals overleaf for details of situations where court approval must first be sought)

B. Assessment of patient's capacity

I confirm that the patient lack capacity to give or withhold consent to this procedure or course of treatments because :

- The patient is unable to comprehend and retain information material to the decision; and / or
- The patient is unable to use and weigh this information in the decision making process; or
- The patient is unconscious

Further details (excluding where patient conscious); for example, how above judgements reached; which colleagues consulted; what attempts made to assist the patient make his or her own decision and why there were not successful.

C. Assessment of patient's best interests

To the best of my knowledge, the patient has not refused this procedure in a valid advance directive. Where possible and appropriate, I have consulted with colleagues and those close to the patient, and I believe the procedure to be in the patient's best interest because:

(Where capacity is likely to be temporary, for example, if patient unconscious, or patient has fluctuating capacity)

The treatment cannot wait until the patient recovers capacity because :

D. Involvement of patient's family and others close to the patient

The final responsibility for determining whether a procedure is in an incapacitated patient's best interest lies with the health professional performing the procedure. However, it is good practice to consult with those close to the patient (e.g. spouse / partner, family and friends, carer, supporter or advocate). Unless you have good reason to believe that the patient would not have wished particular individuals to be consulted, or unless the urgency of their situation prevents this. "Best interest" go far wider than "best medical interest", and include factors such as the patient's wishes and beliefs when competent, their current wishes, their general well being and their spiritual and religious welfare.

(to be signed by a person or persons close to the patient, if they wish)

I / We have been involved in a discussion with the relevant health professionals over the treatment of _____ (patient's name). I / We understand that he / she is unable to give his / her own consent, based on the criteria set out in this form. I / We also understand that treatment can lawfully be provided if it is in his / her best interests to receive it.

Any other comments (including any concerns about the decision)

| | | | |
|--|--|-------------------------|--|
| Name | | Relationship to patient | |
| Address (if not the same as patients) | | | |
| Signature | | Date | |

If a person close to the patient was not available in person, has this matter been discussed in any other way (e.g. over the telephone ?)

Yes No Details

Signature of health professional proposing treatment

The above procedure is, in my clinical judgement, in the best interests of the patient, who lacks capacity to consent for himself / herself. Where possible and appropriate I have discussed the patient's condition with those close to him or her and taken their knowledge of the patient's views and beliefs into account in determining his or her best interest.

I have / have not sought a second opinion

| | | | |
|--------------|--|-----------|--|
| Signed | | Date | |
| Name (Print) | | Job Title | |

Where a second opinion sought, s/he should sign below to confirm agreement

| | | | |
|--------------|--|-----------|--|
| Signed | | Date | |
| Name (Print) | | Job Title | |

Guidance to health professionals (to be read in conjunction with consent policy)

This form should only be used where it would be usual to seek written consent but an adult patient (18 or over) lacks capacity to give or withhold consent to treatment. If an adult has capacity to accept or refuse treatment, you should use Consent Form 1 and respect any refusal. Where treatment is very urgent (for example, if the patient is critically ill), it may not be feasible to fill in a form at the time, but you should document your clinical decisions appropriately afterwards. If treatment is being provided under the authority of Part IV of the Mental Health Act 1983, different legal provisions apply and you are required to fill in more specialised forms (although in some circumstances you may find it helpful to use this form as well). If the adult now lacks capacity, but has clearly refused particular treatment in advance of their loss of capacity (for example in an advance directive or "living will"), then you must abide by that refusal if it was validly made and is applicable to the circumstances. For further information on the laws on consent, see the Department of Health's *Reference guide to consult for examination or treatment* (www.dh.gov.uk)

When treatment can be given to a patient who is unable to consent

For treatment to be given to a patient who is unable to consent, the following **must** apply:

- the patient must lack the capacity (competence) to give or withhold consent to this procedure and
- the procedure must be in the patient's best interests

Capacity

A patient will lack capacity to consent to a particular intervention if he or she is :

- unable to comprehend and retain information material to the decision, especially as to the consequences of having, or not having, the intervention in question ; and / or
- unable to use and weigh this information in the decision making process

Before making a judgement that a patient lacks capacity you must take all steps reasonable in the circumstances to assist the patient in making their own decisions (this will clearly not apply if the patient is unconscious). This may involve explaining what is involved in very simple language, using pictures and communication and decision aids as appropriate. People close to the patient (partner, family, friends and carers) may often be able to help, as may specialist colleagues such as speech and language therapists or learning disability teams, and independent advocates or supporters. Capacity is "Decision specific": a patient may lack capacity to take a particular complex decision but be quite able to take other more straight forward decisions or parts of decisions.

Best Interests

A patient's best interests are not limited to their best medical interests. Other factors which form part of the best interest decision include:

- their wishes and beliefs of the patient when competent
- their current wishes
- their general well-being
- their spiritual and religious welfare

Two incapacitated patient's, who physical condition is identical, may therefore have different best interests. Unless the patient has clearly indicated that particular individuals should not be involved in their care, or unless the urgency of their situation prevents it, you should attempt to involve people close to the patient (partner, family and friends, carer, supporter or advocate).in the decision making process. Those close to the patient cannot require you to provide particular treatment, which you do not believe to be clinically appropriate. However, they will know the patient much better than you do and therefore are likely to be able to provide valuable information about the patient's wishes and values.

Second opinions and court involvement

Where treatment is complex and / or people close to the patient express doubts about the proposed treatment, a second opinion should be sought unless the urgency of the patient's condition prevents this. Donation of regenerative tissue such as bone marrow, sterilization for contraceptive purposes and withdrawal of artificial nutrition or hydration from a patient in PVS must never be undertaken without prior High Court approval. High Court approval can also be sought where there are doubts about the patient's capacity or best interests.

Things to look out for

- **Sore throat, fever, flu like symptoms.**

Please tell your doctor. An extra blood test may be taken to check that your white cells are healthy. Paracetamol can be taken. Ask your pharmacist about other medicines.

- **Weight gain.**

Clozapine treatment is likely to lead to some weight gain. Healthy eating with a good amount of fibre can help this. Do ask for further advice and support if you feel this would be helpful.

- **Seizures and Fits**

These are rare but can occur with high doses. Please see your doctor if you develop any unusual twitching or jerking. Fits can be treated very easily with anticonvulsant medication such as sodium valproate. (Epilim)

- **Driving**

If you find that clozapine makes you feel drowsy, do not drive or use machines. Drinking alcohol in small amounts is safe but it will make you much more sleepy.

How long will I take the tablets for ?

If clozapine works for you it is likely to be a long term treatment. If clozapine has not helped by 6 months to 1 year, it is likely to be gradually stopped.

If there is a problem with your blood results, clozapine will be stopped quickly for safety reasons. Clozapine is not a tranquilliser and is not addictive.

Pregnancy and Breastfeeding

If you are thinking of starting a family or wish to breastfeed, please discuss this with your doctor. This is so that the right checks can be made on you and your child.

Where can I get further information ?

If you wish to know more about clozapine as a treatment, please speak to your prescribing doctor or support worker. The specialist Mental Health Pharmacist can also be asked to come and answer your questions. There are other information sheets available on clozapine.

If you would like to know more about schizophrenia and perhaps meet others who are in similar circumstances, then the addresses below may be of some help to you.

rethink [formerly National Schizophrenia Fellowship]

28 Castle Street
Kingston upon Thames Surrey KT1 2SS
Tel: 0845 456 0455 (Administration)
0208 974 6814 (Advice line - part time hours)

SANE

First floor, Cityside House
40 Adler Street London E1 1EE
Tel: 0207 375 1002 (Administration)
0845 7678 000 (SANELINE 12noon –2am)
www.sane.org.uk

MIND

15 - 19 Broadway
London E15 4BQ
Tel: 0208 519 2122
Info line tel. 0845 766 0163
www.mind.org.uk

This leaflet has been produced by the
Worcestershire Mental Health Partnership
NHS Trust

It is not a substitute for a manufacturer's
information leaflet (rev. Jun05)

Worcestershire 
Mental Health Partnership NHS Trust

Clozapine with Confidence

- Clozapine is used when other antipsychotics have not helped.
- Clozapine consistently achieves better results than other antipsychotics.
- Commitment to clozapine involves having regular blood tests.
- No blood test - no clozapine is for your safety.
- Many people who take clozapine are able to achieve much more.

*Getting the best from your
clozapine medication*

Clozapine with Confidence

Introduction

Clozapine is an antipsychotic medication taken to treat the symptoms of schizophrenia. It is only used when other antipsychotic medicines have not helped. It is available in a number of different brands. Clozaril, Zaponex and Denzapine. In Worcester the Zaponex brand replaced Clozaril in early 2005.

Clozapine is different to other antipsychotic medications. For example, it is stronger in working against psychotic symptoms. In this way it can be better at reducing unpleasant experiences and worrying thoughts. Clozapine also works better against negative symptoms. In this way, it can give you more energy and help you to stay focused on activities.

For many people there are other gains. They may be able to stay out of hospital for longer and possibly do some type of work. Some people do very well on clozapine. For example, they may be able to live on their own for the first time. Like other antipsychotic medicines, clozapine does not work straight away. Some people notice benefit by 6 weeks. For many, improvement is slower. It may take up to 6 months before clear change is seen. For the small number who do not get better the drug can easily be stopped. Stopping clozapine under these conditions is done in a slow and careful way.

Starting Clozapine

Before you can start clozapine you need to have a blood test. This is to check that the white cells and clotting cells (platelets) are healthy. In a small number of cases (1-2%) clozapine can reduce the amount of these important blood cells.

This is why regular blood testing is an important part of being on clozapine. Without a healthy number of white cells you cannot fight off routine infections. Without the right number of platelets, your blood will not clot very well if you cut yourself and you can bruise very easily.

The makers of clozapine have a very safe system in place. It is called the Zaponex Treatment Advisory Service (ZTAS)

At the time of taking the first blood sample you will be registered with ZTAS. Your consultant and the supplying pharmacy are also registered. Pharmacy may only release the next supply of tablets when they get the green light on your blood test.

What is the blood testing schedule ?

This is part of the safe use of the drug and cannot be changed. It is weekly for 18 weeks, fortnightly from 18 weeks until 52 weeks and 4 weekly after the first year. Arrangements will be made to take your blood sample at the most suitable clinic. The blood sample is sent away to the laboratory for analysis. It is not tested to see how much clozapine you have been taking.

Taking the Tablets

Clozapine comes in tablet form only. It is also known as Zaponex, which is the brand name. Please follow the dosing instructions with care. Doses are built up gradually to reduce side effects. If you miss more than 2 days worth of tablets please ask your doctor for advice. He / she may ask you to re-start the tablets gradually.

Side Effects – Does clozapine have any ?

All drugs have side effects. Clozapine has side effects too. Please see below.

Drowsiness, Dizziness on standing

Gets less with time. Helped by taking larger part of dose at night. Take your time when getting up from sitting or lying down.

Excess saliva

Often worse at night - wrap a towel around your pillow. Ask your doctor or pharmacist about tablets that may help with this.

Constipation

Increasing the amount of fibre in the diet can help. Ask your pharmacist about a choice of laxative. Do not ignore this side effect.

Palpitations

Some people may get a fast heart beat. This is not dangerous but do tell your doctor. He / she may advise some medication to slow the heart down.

Many of the side effects are short term and are lessened by introducing the drug gradually. Unlike older antipsychotics such as haloperidol and chlorpromazine, clozapine does not cause movement related side effects (eg Parkinsonism).

It should not affect your sex life either.

Please tell your doctor about any side effects that you may be worried about.

