1. Introduction

The management of patients with some conditions can be complicated, and as a result it may not be possible to fully discharge patients from hospital back to the care of their General Practitioner (GP). Therefore, a system of Shared Care encompassing primary and hospital out-patient care is appropriate. Drugs requiring a shared-care arrangement may be defined as “those drugs requiring a complex level of monitoring which is likely to exceed the expected expertise of the prescriber”.

Near patient testing (NPT) relates to drugs from the shared-care list “initially requiring a complex level of monitoring which is likely to exceed the expected expertise of the prescriber”. There is a nationally-agreed list of drugs where monitoring is undertaken in primary care through an enhanced national or local service agreement. A general practice is accredited and paid for undertaking this enhanced service. A summary of the areas of responsibility for drug treatment is provided in the table.

<table>
<thead>
<tr>
<th>Cardiff and Vale Formulary Categories and prescribing responsibilities for Shared Care</th>
<th>prescribing</th>
<th>monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General (G)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initiation, stabilisation and ongoing monitoring could be undertaken by any prescriber including Primary Care.</td>
<td>Primary or secondary care</td>
<td>Primary or secondary care</td>
</tr>
</tbody>
</table>

| **Specialist Recommended (R)** |             |            |
| The recommendation to use a specific medicine is made by a specialist but there is no need for the specialist to initiate the medication. | Primary or secondary care | Primary or secondary care |

| **Specialist Initiated (S)** |             |            |
| Initiation and stabilisation should be undertaken by a specialist but follow-up prescriptions may be issued by any prescriber. | Secondary care and then Primary Care | Primary or secondary care |

| **Specialist initiated with a Shared Care Protocol S-SCP** |             |            |
| Initiation, stabilisation and on-going monitoring should be undertaken by a specialist, but follow-up prescriptions may be issued by any prescriber following agreement to share care, in accordance with the protocol. | Secondary care then primary care following GP agreement | Secondary care |
| Note: near patient testing is subject to enhanced service agreement | | |

| **Specialist initiated with a Shared Care Protocol and Near Patient Testing (NES/LES)* S-NPT** |             |            |
| Prescribing and monitoring responsibility remains with a specialist. Prescriptions are normally issued from secondary care or use only applies in a secondary care setting. Any exception to this should be supported by an approved protocol(s) | Secondary care then primary care following GP agreement | Secondary care then primary care following GP agreement (accredited GP monitoring commissioned by UHB) |

| **Hospital Only (H)** |             |            |
| Available following approval by Clinical Board Director only | As appropriate | As appropriate |

* NES=national enhanced service, LES=local enhanced service
An appropriate specialist will recommend if a drug is appropriate for Shared Care, and should indicate this on a formulary application to the appropriate Clinical Board Medicines Management Group (CB MMG). If the CB MMG approves the application and has agreement from Primary, Community and Intermediate Care (PCIC) CB MMG, the applicant will be requested to produce a draft Shared Care Protocol. This will be discussed by the Shared Care Group and once approved by them will be forwarded with the application for final ratification at C&V corporate Management Group (cMMG). The list of drugs suitable for Shared Care (and Near Patient Testing) will be agreed by C&V cMMG and the Local Medical Committee (LMC) (Appendix 1).

This document sets out specific referral procedures and areas of responsibility of the Hospital Consultant and General Practitioner (GP) for those patients who require Shared Care. A model document is attached, (Appendix 2) that is used as a framework for Shared Care Protocols. All protocols are developed with the appropriate Clinical Directorates and approved by the C&V cMMG.

2. Consultant responsibilities

A. Stabilisation and request for Shared Care
The Consultant will:
1. Ensure all initial necessary tests are undertaken.
3. Decide if Shared Care is appropriate for the patient.
4. Contact the GP to invite participation in Shared Care and/or Near Patient Testing by sending an advance request, together with the Shared Care Protocol (Appendix 3).
5. Arrange for hospital supply of medication until in the opinion of the Consultant the patient's condition is stable.
6. The hospital recognises that the GP has the right to refuse to agree to Shared Care. In such an event the total clinical responsibility for the patient for the diagnosed condition will remain with the Consultant.

B. Initiate and Review
1. Send a letter (Appendix 4) to the GP when the patient is stable, “handing over” the Shared Care and Near Patient Testing (where commissioned) of the patient to the GP (only if a positive response to the SC request has been received from the GP).
2. A minimum of a further two weeks supply of the drug will be dispensed by the hospital. Where appropriate, the patient will be issued with a drug monitoring record card.
3. In cases where the drug is not easily obtained in the community the hospital pharmacist will attempt to contact a local pharmacist (designated by the patient) to give advance warning of the agreement to Shared Care and ensure that a supply can be obtained.
4. The hospital will arrange regular out-patient assessment depending on clinical circumstances and will see the patient at the GP's request e.g. where the Shared Care Protocol indicates need for a review. The assessments will include clinical monitoring as set out in the protocol.
5. The hospital will notify the GP of any change in the patient's status including the dose, frequency and form of the drugs currently prescribed.
6. Whenever the patient is seen by the Consultant, he/she will send a written summary within 14 days to the patient's GP.
7. The Consultant will inform the GP of a contact number and ensure that they or their representative will be available to provide information or advice to the GP.

3. GP responsibilities

A. Consider and Respond
The General Practitioner:
1. Following receipt of the advance Shared Care request form (Appendix 3) will ensure that he/she has the information and knowledge to understand the therapeutic issues relating to the patients medical condition and the facilities to comply with the protocol.
2. Within one week of receipt of the request, will return the completed Shared Care Request form (Appendix 3) response to indicate whether he/she is willing to undertake Shared Care and/or Near Patient Testing when the patient is stabilised.
3. Take over the Shared Care and Near Patient Testing (where commissioned) of the patient once a letter (Appendix 4) has been received from the Consultant indicating that the patient has been stabilised on the SC drug.

B. Maintain and Communicate
The General Practitioner will
1. Prescribe the maintenance therapy in accordance with the Consultant request.
2. Monitor and record the therapy in accordance with the appropriate Shared Care Protocol.
3. Report any adverse events in the treatment of the patient to the Consultant, as well as to the usual bodies e.g. Medicines and Health Care products Regulatory Agency (MHRA).

IMPORTANT: Whoever prescribes the medication will be considered to be clinically responsible.

4. UHB (through locality teams) responsibilities

A. Educate and accredit
C&V UHB will ensure that information about Shared Care and Near Patient Testing systems is disseminated to general practitioners. The UHB will accredit those GP practices which meet the appropriate criteria e.g. have an accredited prescriber. A list of accredited practices will be maintained and made available to the UHB.

B. Encourage appropriate management
C&V UHB will encourage GPs to enter into Shared Care agreements when:
   After receiving specialist advice, the GP is of the medical opinion that the patient should receive the treatment.
The GP is confident that he/she can accept clinical responsibility.
The holistic care provided by the GP represents a better service to the patient than traditional separate care.

C. Consider cost implications
Practices will not be penalised for prescribing high cost drugs which are subject to a Shared Care Protocol.
Practices will be informed of the above when their prescribing budgets are issued.

Other responsibilities
A. The Clinical Board MMGs will consider the need for Shared Care arrangements when responding to new drug applications and considering agents approved by NICE or AWMSG. This will be included in any recommendations provided to the C&V corporate MMG.

B. The C &V corporate MMG will liaise with Clinical Board MMGs and the Local Medical Committee to agree the list of drugs suitable for Shared Care and Near Patient Testing arrangements. The C&V Shared Care Group will agree the content of Shared Care and Near Patient Testing Protocols for local use.

C. The Shared Care Group (on behalf of C&V corporate MMG) will make arrangements for the regular review and updating of the list of Shared Care/Near Patient Testing drugs and the individual protocols. The Group will ensure appropriate dissemination of any changes to the relevant areas of practice.

D. When requested, the C&V Shared Care Group (on behalf of corporate MMG) will audit the implementation of Shared Care/Near Patient Testing procedures. This will be undertaken by the relevant CB MMG or Directorate. This should be reported to the Shared Care Group who will escalate to corporate MMG where necessary.
<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Protocol Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone</td>
<td>Severe cardiac rhythm disorders</td>
<td>CV 44</td>
</tr>
<tr>
<td>Apomorphine</td>
<td>Disabling motor fluctuations in Parkinson’s disease</td>
<td>CV 02</td>
</tr>
<tr>
<td>Atomoxetine</td>
<td>Attention Deficit Hyperactivity Disorder (ADHD), Hyperkinetic Disorder (HKD) in children 6 years and older, adolescents and adults who began treatment during childhood</td>
<td>CV 46</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>Autoimmune conditions usually where corticosteroid therapy alone provides inadequate control</td>
<td>CV 51</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>Liver transplantation</td>
<td>CV 04</td>
</tr>
<tr>
<td>Ciclosporin</td>
<td>Rheumatoid arthritis</td>
<td>CV 29</td>
</tr>
<tr>
<td>Disulfiram</td>
<td>Maintenance of abstinence in alcohol</td>
<td>CV 20</td>
</tr>
<tr>
<td>Dornase alfa</td>
<td>Cystic fibrosis</td>
<td>CV 38</td>
</tr>
<tr>
<td>Ketamine</td>
<td>Pain in a palliative care setting not responding to opioids and adjuvant therapy.</td>
<td>CV 10</td>
</tr>
<tr>
<td>Lanreotide</td>
<td>Acromegaly, carcinoid syndrome and other peptide hormone secreting tumours</td>
<td>CV 40</td>
</tr>
<tr>
<td>Leflunomide</td>
<td>Rheumatoid arthritis and Psoriatic arthritis</td>
<td>CV 11</td>
</tr>
<tr>
<td>Leuprorelin</td>
<td>Precocious puberty</td>
<td>CV 22</td>
</tr>
<tr>
<td>Lisdexamfetamine</td>
<td>Attention deficit hyperactivity disorder (ADHD) as part of a comprehensive treatment programme in children aged 6 years of age and over.</td>
<td>CV 57</td>
</tr>
<tr>
<td>Lithium</td>
<td>Prophylaxis of mania, bipolar disorder, recurrent depression</td>
<td>CV 12</td>
</tr>
<tr>
<td>Melatonin</td>
<td>For children and adolescents (up to and including 18 years) with significant sleep onset difficulties</td>
<td>CV 54</td>
</tr>
<tr>
<td>6-Mercaptopurine</td>
<td>Inflammatory Bowel Disease</td>
<td>CV 25</td>
</tr>
<tr>
<td>Methadone</td>
<td>Pain requiring methadone for control</td>
<td>CV 14</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>Rheumatoid arthritis and various auto-immune conditions usually when corticosteroid therapy alone provides inadequate control</td>
<td>CV 55</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>ADHD, Hyperkinetic disorder</td>
<td>CV 42</td>
</tr>
<tr>
<td>Mycophenolate mofetil</td>
<td>Various conditions which characteristically respond to immune suppressive therapy.</td>
<td>CV 53</td>
</tr>
<tr>
<td>Octreotide LAR</td>
<td>Acromegaly, carcinoid syndrome and other peptide hormone secreting tumours</td>
<td>CV 33</td>
</tr>
<tr>
<td>Octreotide</td>
<td>Palliative care</td>
<td>CV 16</td>
</tr>
<tr>
<td>Penicillamine</td>
<td>Rheumatoid arthritis</td>
<td>CV 17</td>
</tr>
<tr>
<td>Riluzole</td>
<td>Motor neurone disease (MND)</td>
<td>CV 39</td>
</tr>
<tr>
<td>Sodium aurothiomolate</td>
<td>Rheumatoid arthritis</td>
<td>CV 19</td>
</tr>
<tr>
<td>Somatropin</td>
<td>Growth hormone in children</td>
<td>CV 27</td>
</tr>
<tr>
<td>Somatropin</td>
<td>Adult Growth disorders</td>
<td>CV 34</td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>Inflammatory Bowel Disease</td>
<td>CV 41</td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>Rheumatoid arthritis</td>
<td>CV 21</td>
</tr>
<tr>
<td>Tacrolimus</td>
<td>Liver transplantation</td>
<td>CV 43</td>
</tr>
<tr>
<td>Tobramycin nebuliser solution</td>
<td>Chronic colonisation with \textit{pseudomonas aeruginosa} in Cystic fibrosis</td>
<td>CV 48</td>
</tr>
<tr>
<td>Triptorelin</td>
<td>Precocious puberty</td>
<td>CV 23</td>
</tr>
</tbody>
</table>
Appendix 2

Cardiff and Vale Standard Format for Shared Care Protocol/Near Patient Testing

**DRUG: **

**PROTOCOL NUMBER:**

**INDICATION:**

**General guidance**

This protocol sets out details for the Shared Care (SC) of patients taking XXXXXXX and should be read in conjunction with the General Guidelines for Shared Care. Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. The **doctor who prescribed the medication legally assumes responsibility for the drug and the consequences of its use**. The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient’s condition.

**Background**

A short summary of the need for Shared Care of patients using the drug. A statement of the indication for use of the drug. Where appropriate, referral criteria for drug(s).

**Responsibilities**

**A. Consultant responsibilities**

1. When treatment is **initiated** send Shared Care/Near Patient Testing (where commissioned) request form (Appendix 3) to GP with Shared Care Protocol.
2.Baseline and continued monitoring until patient is stabilised of biochemical and/or haematological and/or clinical parameters. (If Near Patient Testing (NPT) not agreed then monitoring will be continued after patient is stabilised).
3. Initiate therapy following full discussion with the patient of benefits and risks.
4. *(For drugs that can cause blood disorders)* The patient will be informed to contact their GP immediately if any of the following occur: sore throat, fever, infection, non-specific illness, unexplained bleeding and bruising, purpura, mouth ulcers or rashes develop.
5. *(For drugs that are teratogenic)* To counsel patients to take contraceptive precautions during treatment or during and after (specify time) after treatment. Record in GP referral letter that contraceptive advice has been given.
7. Titrate DRUG, adjusting dose as appropriate and undertake monitoring of clinical response and side effects.
8. When a GP positive response to SC has been received and patient has been stabilised send a letter (Appendix 4) to GP “handing over” the Shared Care and Near Patient Testing (where commissioned) of the patient to the GP.
9. Respond to any request from GP to review the patient due to adverse effects of therapy.
10. Advise the GP on continuing or stopping DRUG following medical review of the patient and associated drug therapy.
11. If Near Patient Testing not agreed notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action.

**B. GP responsibilities.**

1. Within one week of receipt, return the completed Shared Care request form to indicate whether or not willing to undertake Shared Care.
2. Prescribe DRUG as part of the Shared Care agreement.
3. Monitor the general health of the patient.
4. Where Near Patient Testing is agreed monitor the parameters indicated (see page X), document results in the patient’s monitoring booklet and report to and seek advice from the Consultant on any aspect of patient care which is of concern.
5. Report adverse effects of therapy to the Consultant and the Medicines and Health Care products Regulatory Agency (MHRA).
6. If Near Patient Testing not agreed, to act on advice provided by the Consultant if patient does not attend for appropriate monitoring.
7. (For patients with immunosuppression because of disease or treatment) recommend that patient receives pneumococcal vaccination and annual influenza vaccination.

Dosage Regimen
A statement of the usual dosages including formulation, frequency and the rationale for adjustment.

Monitoring
Clear indication of tests to be done including frequency, responsibilities and causes for adjustment or referral.

Where Near Patient Testing applies, the criteria for referral back to the Shared Care (hospital) monitoring will be specified.

Adverse effects
Reference to the Summary of Product Characteristics (SPC) within this section is acceptable but in addition the most common adverse effect should be listed together with guidance on when to refer to the hospital.

Interactions
The significant interactions should be listed together with a procedure for enquiring about particular problems.

Special recommendations
An indication should be given of the need to give or to avoid specific treatment.

Date of approval  Date of review

Appendix 3
Cardiff and Vale - Consultant Request - Shared Care / Near Patient Testing (NPT)

Date:

To: Dr.

Name of patient________________________ (attach addressograph)

Diagnosed condition __________________________

Your patient has been started on --------------------------- A copy of the Shared Care Protocol is attached SCP No.... This is an ADVANCE request for your agreement to sharing the care of this patient. I will write to you when the patient is stable but would be grateful if you could return this form to me within a week. You will not be expected to prescribe (or monitor if NPT drug) until you have received the letter stating the patient has been stabilised.

Contact Telephone No.  Consultant Name

Signature _________________________________

Department __________________ Date __________

Hospital _________________________________
GP RESPONSE Please tick as appropriate

A. I will be willing to undertake when patient has been stabilised in secondary care
   Shared care/NPT □
   Shared care □

B. I am unable to undertake Shared Care for this patient □ - please tick reason(s) below
   Practice does not participate in Shared Care □
   Training issues □
   Unwilling to take responsibility for prescribing this drug □
   Time issues □
   Other-please state ------------------
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

   GP signature_________________________ Date __________

   Practice Address/Stamp ________________________________

   (Please return whole completed form or a photocopy to (Name) ________________
   (Address)________________________

   If you need to discuss before returning please contact (Name) ____________

   Telephone Number ________________

Appendix 4

Cardiff and Vale - Letter To GP - To Confirm Patient Is Stable On Shared Care Drug

Do not send unless GP has returned the Shared Care request form and has accepted Shared Care for this patient. Please refer to the Shared Care Protocol for full prescribing and monitoring information.

Date

To Dr.

Name of patient_________________________ (attach addressograph)

Diagnosis ________________________________

Drug name

Dose

Any further patient details (if necessary)

Please indicate which option is appropriate by crossing through a) or b).

a) Thank you for agreeing to undertake Shared Care for the above patient. He/she is now stable. Please will you arrange for (drug name) to be added to the patient’s repeat prescription.

b) Thank you for agreeing to undertake Shared Care and Near Patient Testing for the above patient. He/she is now stable. Please will you arrange for ________________ to be added to the patient’s repeat
prescription. The patient is aware that he/she needs to make a monitoring appointment at your surgery in ........ weeks time.

**The patient has been issued with at least 14 days supply of (drug name).**

If there are any problems relating to the care of this patient then please contact.

Name ..............

Telephone number ......................

**Appendix 5**

**Cardiff and Vale Criteria for Shared Care**

1. Therapy is for a licensed indication for a chronic condition. Occasionally a drug that has a recognised (but unlicensed) indication may be considered suitable for Shared Care.
2. There is sufficient evidence for its use over existing preparations. Shared care is therefore not appropriate where clinical experience is limited or side effects yet to be established.
3. Therapy is initiated and stabilised in secondary care. The need for stabilisation will vary with different drugs, patients and local agreement.
4. Drug administration and monitoring does not require specialist equipment or skills.
5. Adequate follow-up can be provided by secondary care.
6. The safety profile of the drug is such that inadequate monitoring may have serious implications.
7. The service to the patient is convenient and appropriate to their needs.
8. Safety: If the patient must attend the specialist on a regular basis (for reasons other than obtaining a prescription) then it may be more appropriate for prescribing to stay with secondary care.
9. Involvement of primary care does not introduce unnecessary duplication.
10. A comprehensive Shared Care Protocol for the drug is available.
11. The use of resources by NHS Wales is efficient.
12. The physician signing the prescription takes legal responsibility. Consideration will need to be given to local body of professional opinion such as LMC as to whether Shared Care of this drug is appropriate.
13. Transferring prescribing between primary and secondary care for purely budgetary reasons is not appropriate.
Appendix 6

Cardiff and Vale - Shared Care-Patient Consent

Patient consent to participate in Shared Care for -----------------------------

Patient name ------------------------

Address --------------------------

Date of birth ----------------------

As you are taking the drug, ----------------~, it is important that you are monitored.

This will require you to have the following blood tests:-

<table>
<thead>
<tr>
<th>Test</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In order to ensure safe prescribing you will -

1. Attend for regular blood tests as advised
2. Be responsible for contacting the surgery within 24 hours (excluding weekends and bank holidays) of your blood test and asking for the result.
3. Be responsible for taking the required dosage as advised by the Practice/ Hospital.
4. Attend hospital appointments (with respect to this drug) as appropriate and notify the hospital if unable to attend for a booked appointment.
5. Be responsible for contacting the surgery if unable to attend for a booked appointment.

By signing this contract, you agree to attend the Surgery/Hospital for the appropriate tests/monitoring.

A copy of this contract will be placed in your medical record and you will be given a copy to keep for your information.

I have read, understood and accept the above.

Signed --------------------------

Date --------------------------