Standards for the Safe Use of Oral Anticancer Medicines

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<td>30th May 2008</td>
<td>Initial Draft document</td>
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<tr>
<td>11th June 2008</td>
<td>Haemato-Oncology Tumour Working Group</td>
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<tr>
<td>18th June 08</td>
<td>Comments incorporated from the following:</td>
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<td>27th June 08</td>
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<tr>
<td>27th June 08</td>
<td>Comments incorporated from Dr Nic Ketley, Chair SELCN DTAC</td>
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<tr>
<td>3rd July 2008</td>
<td>Network Pharmacists and Lead Chemotherapy Nurses Group</td>
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<td>Network Drugs &amp; Therapeutics Advisory Committee</td>
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<td>11th July 2008</td>
<td>Haematology &amp; Oncology Clinical Governance &amp; Risk Management Group</td>
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<td>29th July 2008</td>
<td>GSTFT Drugs &amp; Therapeutics Committee</td>
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<tr>
<td>8th Sept 2008</td>
<td>Comments from GSTFT D&amp;T incorporated</td>
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<td>25th Sept 2008</td>
<td>GSTFT Clinical Governance &amp; Risk Management Group</td>
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<tr>
<td>6th Nov 2008</td>
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<td>9th Dec 2008</td>
<td>SELCN Board</td>
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<tr>
<td>October 2012</td>
<td>Comments from Jacky Turner incorporated</td>
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<tr>
<td>24th October 2012</td>
<td>DTAC Approved update</td>
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1 Background

The National Patient Safety Agency (NPSA) issued a Rapid Response Report alerting all healthcare staff involved in the use of oral anticancer medicines of potentially fatal outcomes if incorrect doses of oral anticancer therapy are prescribed, dispensed or administered. This outlined actions the NHS and independent sector must undertake. The overriding principle of this document is that oral anti-cancer medicines are managed to at least the same standards as IV chemotherapy/ IV anti-cancer medicines.

Standards for dealing with adult systemic therapy chemotherapy are clearly defined in the Manual for Cancer Services, revised in 2011. The SELCN Service Specification for Adult Systemic Cancer Therapy (Feb 2007) outlines the service requirements for systemic cancer therapy services for adults across SE London. The service standards outlined in that document relating to acquisition, preparation & handling, prescribing, facilities administration, waste disposal, organisation, health & safety, storage portering and transportation, protocols, out of hours and supportive care, training, quality standards and clinical governance, communication and record keeping apply equally to oral anticancer medicines as to those administered by the intravenous route.

The NPSA require Healthcare organisations to prepare local policies and procedures that describe the safe use of these oral medicines. Introduction of the best practice standards outlined in this document will ensure Healthcare organisations in the South East London Cancer Network (SELCN) meet the NPSA requirements. The Service specification will need to be reviewed in the light of the NPSA guidance, the Systemic Anti-Cancer Therapy: For better, for worse? report issued by NCEPOD in 2008 and the report entitled Chemotherapy Services in England: Ensuring quality and safety, DH August 2009 issued by the National Chemotherapy Advisory Group. This document serves to bridge the gap and recommend standards for oral chemotherapy in SELCN, currently not covered in the service specification.

For the purposes of this document the term "Oral Anticancer Medicine’ is used to refer to all drugs with direct anti-tumour activity, orally administered to cancer patients, including traditional cytotoxic chemotherapy such as capecitabine, hydroxyurea, chlorambucil and small molecule/ antibody treatments such as imatinib, erlotinib, sunitinib and other agents such as thalidomide or lenalidomide. It will include new anticancer medicines that become licensed and approved for use by Trust formularies for cancer indications. It does not include hormonal or anti-hormonal agents such as tamoxifen and aromatase inhibitors.

It must be noted that some oral anticancer medicines are also used for non-cancer indications, e.g. methotrexate for rheumatoid arthritis, and pose similar risks to the patient. The NPSA recommends organisations to undertake a risk assessment and their guidance applied as appropriate. SELCN advises the same approach for the application of these standards for non-cancer patients.

Standards for delivery of oral anticancer medicines for children will be defined by the Paediatric primary treatment centres where the anticancer treatment for these patients is initiated. It is recommended, however, that the broad principles of this document apply equally to children receiving these medicines.

2 Scope

This document outlines the standards to be followed by all organisations and staff involved in the prescribing, dispensing, supply, administration and monitoring of the use of oral anticancer medicines in SELCN. This includes all secondary care and primary care organisations.

It is the responsibility of Primary Care Trusts to ensure compliance with these standards within primary care and the responsibility of Acute Trusts to ensure compliance within the secondary care setting.

3 Audit

It is important that these standards are adopted in all areas where oral anticancer medicines are prescribed dispensed or administered.
It is recommended that Trusts (Acute Trusts and Primary Care Trusts) should put systems in place in order to allow audit of the standards to, as far as practically possible, occur prospectively. In areas where this is not possible, audit should be done retrospectively. Each respective Trust is accountable for implementation of these standards and for auditing their compliance.
4 SELCN STANDARDS FOR PRESCRIBING OF ORAL ANTICANCER MEDICINES

The prescribing of oral anticancer medicines must be carried out and monitored to the same standards as those for parenteral (IV) chemotherapy.

4.1 SECONDARY CARE

Each secondary Care organisation must nominate a clinical lead for oral anticancer medicines.

♦ Note: Good practice would be for this to be the same person who is responsible for IV chemotherapy (Head of Chemotherapy Service Peer Review 11-3S-101) to ensure consistency of standards. The clinical lead must work with Trust Management, Lead Clinician for Cancer, Chemotherapy Lead, Head of Pharmacy and Lead Cancer Nurse to ensure these standards are enforced.

4.1.1 Medical Prescribing

Standards for medical prescribing of systemic cancer therapy are described in the SELCN Service Specification, Trust policies/codes of practice for prescribing, and apply equally to oral anticancer medicines.

4.1.2 Non-medical prescribing

Non-medical prescribers (NMPs) may prescribe the second and subsequent cycle of oral anticancer medicines provided they have acquired approval from their organisation and are working within an agreed clinical management plan (supplementary NMPs) or following a treatment plan (independent NMPs).

♦ Note: Good practice would be for approval to be given by the clinical lead for oral anticancer medicines after discussion at the local chemotherapy group (or equivalent).

4.1.3 Initiation of treatment

Initiation of a course of treatment with oral anticancer medicines must only be undertaken by a cancer specialist.

All prescribers initiating treatment for oral anticancer medicines must (in all treatment settings, i.e. outpatients, day case or inpatients):

♦ assess the patient’s suitability for oral treatment including ability to swallow tablets or capsules
♦ assess patient’s ability to comply with the proposed drug/regimen
♦ obtain consent from the patient following local Trust protocol
♦ provide verbal and written information about their oral anticancer therapy in the form of a treatment plan
♦ Provide the patient with a SELCN Hand Held record booklet and complete patient details within it as appropriate.
♦ ensure appropriate communication to patient’s GP and referring consultant about the medicines, ensuring the GP is clear on the role they play in managing patient. Note: caution must be taken if Trusts issue a copy of ‘prescriptions’ to GPs as there is a risk of inappropriate continuation of medicine. It must be stated on any written communication that ‘This medication is NOT for continuation by primary care’
♦ ensure patients are appropriately counselled on the use of their medicines. Note: this information may be provided/reinforced by pharmacist/nurse according to local policy.
♦ Note: Good practice would be to ensure all these checks have been undertaken on second and subsequent cycles.

Trusts may want to consider this assessment to being undertaken by appropriate nursing staff, for example using a checklist.

4.1.4 Inpatient Prescribing (on admission)

Patients admitted to hospital wards on oral anticancer medicines are at risk from uncontrolled prescribing. A detailed medication history must be taken on admission, including:

♦ indication for oral anticancer therapy
♦ drug(s) and dose(s), frequency of administration, e.g. daily, weekly, continuous or cyclical
4.1.5 Prescribing for External Healthcare Organisations

All prescribers who write prescriptions for oral anticancer medicines for patients who will have the medicines administered in organisations external to their Trust, e.g. nursing homes, prisons, children’s homes must ensure that the external organisation has access to the specified regimens and protocols as detailed below.

In the case of organisations such as prisons where medications are re-prescribed by the prison’s medical officer in accordance with their own procedures it is recommended that the organisation ensures regimens and protocols are always obtained before re-prescribing.  

Note: Good Practice could be to ensure the external organisation is informed that these standards will be available on the South East London Cancer Network website (http://www.selcn.nhs.uk).

4.1.6 Written protocols

Standards of written protocols for systemic cancer therapy are described in the SELCN Service Specification and apply equally to oral anticancer medicines.

Note- Good practice would be for a copy of the specific protocol to be filed in the patient’s notes. Copies of protocols, ideally in electronic format, should be available on all wards where oral anticancer medicines are routinely administered or where patients receiving oral anticancer medicines may be admitted (e.g. emergency admissions wards).
Prescribers must have access to the agreed drug protocols for the regimens in use. The BNF is not recommended as a primary source of anticancer drug prescribing information. Chemotherapy regimen protocols can be found on the Network website: http://www.selcn.nhs.uk

4.1.7 Treatment plans
The patients treatment plan must be recorded in their healthcare records and in their SELCN Hand Held record,
This will include:
♦ The planned course of treatment, including details of the medicines and when they should be taken (i.e. daily, weekly or for a specified number of days)
♦ The frequency of patient visits for ongoing monitoring of treatment
♦ Likely toxicities related to the particular regimen.
♦ Contact details for specialist advice and name of key worker

4.1.8 Deviation from agreed protocols
All intended deviations from protocol, such as dose modifications, should be clearly identified as such and recorded in patient’s healthcare records, in their SELCN Hand Held Record and on the prescription form and communicated to the patient’s GP and referring consultant. Pharmacy must be notified.

4.1.9 Repeat prescription
Oral anticancer medicines must not be prescribed by repeat prescriptions.

4.1.10 Prescription forms
Standards for prescriptions for systemic cancer therapy are described in the SELCN Service Specification and apply equally to oral anticancer medicines. In addition to the standards outlined in the Service Specification prescriptions must contain:
♦ number of days or doses to be dispensed (expressed in words and figures e.g. for three (3) days not 3/7 – abbreviations are not to be used)
♦ the intended start date and exact duration of treatment including either stop date or the word ‘ONLY’ to indicate that the medicine is not continuous, e.g. capecitabine start on 1/1/08 for 14 days ONLY
♦ for continuous treatment – the intended review date should be written in the patient’s Hand Held record.

Pre-printed prescriptions must be clear and unambiguous and available to all prescribers. They must be ‘secured’ to prevent accidental changes to the pre-printed information and subject to appropriate levels of documentation control, e.g. a master copy approved by a different person to that who prepared the document.

4.2 PRIMARY CARE

There should be no prescribing of systemic, including oral, cytotoxic chemotherapy, or intracavitary cytotoxic chemotherapy for the treatment of malignant disease in primary care. This does not apply to:

♦ GPs who are acting for that part of their practice under contract to a hospital Trust
♦ The prescription of oral hydroxyxcarbamide, for cases under overall care of a hospital consultant haemato-oncologist
♦ The prescription of topical cytotoxic agents used for the treatment of some skin malignancies or premalignant conditions
♦ The Medicines Management Team will regularly monitor the prescribing of cytotoxic agents and practices will be informed if prescribing of these agents is identified.
5 STANDARDS FOR DISPENSING AND SUPPLY OF ORAL ANTICANCER MEDICINES

5.1 SECONDARY CARE

Trust pharmacy departments dispensing oral anticancer medicines should operate to the same safety standards used when preparing and dispensing parenteral (IV) chemotherapy.

5.1.1. Access to written protocols and treatment plans

In order to confirm the patient’s treatment plan, pharmacy staff verifying the prescription should do so by asking to see the patient’s SELCN Hand Held Record (HHR) which will contain the treatment plan. For inpatients, see section above.
If the patient forgets to bring their HHR to the clinic, a new temporary treatment plan should be issued by the prescribing doctor in clinic. If a temporary treatment plan is issued, at the next patient visit the HHR should be reconciled by the prescriber.
Pharmacy staff must have access to the agreed drug protocols for the regimens in use.
The BNF is not recommended as a primary source of anticancer drug prescribing information.
Chemotherapy regimen protocols can be found on the Network website: http://www.selcn.nhs.uk

5.1.2. Prescription verification

Standards for verification of prescriptions for systemic cancer therapy are described in the SELCN Service Specification and apply equally to oral anticancer medicines.
• Note - the SELCN pharmacy group have defined the local training standards for oncology pharmacists based on the BOPA competency framework.

5.1.3. Computer Generated Prescriptions

Standards for prescriptions for systemic cancer therapy are described in the SELCN Service Specification and apply equally to oral anticancer medicines In the event of receiving handwritten prescriptions pharmacists must contact prescribers and ask for prescriptions to be re-issued on computer generated specific oral anticancer prescription forms.
In the rare incidence that a computer generated regimen specific prescription form is not available a generic oral anticancer prescription may be used with all details listed above entered on the prescription.
Pharmacists must not accept prescriptions handwritten on out-patient prescription pads.

5.1.4. Training of pharmacy staff

It is recognised that it may not be possible to ensure that all oral prescriptions are checked by a trained oncology pharmacist. Trusts must therefore ensure that appropriate training on the safety aspects of oral anticancer medicines is provided to pharmacy staff involved in dispensing and supply of these medicines. This training must be rolled out to existing staff and must also be undertaken as part of induction process for new staff and repeated at regular intervals, for all staff involved in dispensing and supply of oral anti-cancer medicines.

5.1.5. Access to Oncology Pharmacy advice

In order to support staff involved in the dispensing and supply of oral anticancer medicines, there must always be available in the organisation a trained oncology pharmacist who is able to provide oncology pharmacy advice to dispensary staff.
• Note: Trained oncology pharmacists are those who are deemed competent to check and authorise IV chemotherapy prescriptions and are competent to provide pharmaceutical care to cancer patients.

5.1.6. Dispensary Standards

• Pharmacists validating oral anticancer medicine prescriptions should calculate the exact amount (number of tablets/capsules) to be supplied when validating the prescription. The prescription must then be endorsed with the correct quantity to be supplied.
• The pharmacist must ensure the directions on the prescription are clear and unambiguous and include, where relevant, the intended period of treatment, including start and stop dates for short term or intermittent treatment.
• The exact quantity of tablets/capsules required must be supplied unless a risk assessment of a particular drug pack size/type identifies it as not suitable to be split. The quantity calculated by the pharmacist must be subject to a second independent check during the dispensing process. Wherever possible only packs that can be safely split will be purchased.
• The quantity must be physically checked by counting the number of tablets/capsules supplied.
• A different member of staff should final check the prescription from pharmacist who validated the prescription. Ideally the dispensed prescription should be subject to a second independent check which could be by the validating pharmacist.
• Where a pharmacist is working alone (for example, as part of an on-call or residency service) the individual must ensure that appropriate investigations have taken place to ensure it is appropriate to make the supply of an oral anticancer medicine (see section 4.1.4). It is recommended that doses of oral anticancer medicines are withheld until the patient's medication history, treatment plan and assessment for continued treatment are confirmed. If the supply is made, under these conditions, the individual should undertake a second dispensing check themselves.
• All patients must receive a manufacturer's Patient Information Leaflet, with their oral anticancer medicines.
• Pharmacy staff must not break or crush tablets, capsules must not be opened. Queries about difficulties in taking the oral form should be directed to a specialist pharmacist. Use of a suspension or solution is preferred and a suitable preparation must be obtained from an NHS hospital pharmacy or commercial compounding/manufacturing facility with appropriate safe-handling facilities. It must be noted that in many cases there are no liquid alternatives, in these cases refer back to original prescriber.
• Use of compliance aids is not routinely recommended except for elderly patients or those on more complex regimens, e.g. CDT, should be given a Medication compliance aid to help with compliance. If there is thought to be a need, a risk assessment must be undertaken and documented in the patient’s healthcare records. It is not possible to supply medication in compliance aids to out-patients. The prescriber must be contacted if the pharmacist has doubts about the patient's ability to safely self-administer their chemotherapy.
• Label directions must be clear and unambiguous and include where relevant; the intended period of treatment; start and stop dates or the number of days expressed as ‘for X days ONLY’ to indicate that the medicine is not continuous (for short term or intermittent treatment); an appropriate indication of the need for safe handling. Any ambiguities must be referred back to the validating pharmacist/prescriber.
• If more than one tablet strength is supplied in order to make up the correct dose, the label for each strength should refer to the other tablet size and also state the total dose to be taken.

5.1.7. Supply to Inpatients
Where possible the patient’s own medicines must be used. Temporary stocks must not be used. All anticancer medicines must be dispensed and labelled to include the following information:
• patient name
• generic drug name
• strength of tablets or capsules, or concentration of oral liquid
• the number of tablets / capsules in the container, or volume of liquid
• administration instructions
• length of treatment, including stop date as appropriate
• storage conditions
• Caution: Cytotoxic Drug (as appropriate)
• name and address of pharmacy department

N.B. Patients should be advised to return any unused oral anticancer medication that they may have at home.

5.1.8. Supply to External Healthcare Organisations
• Trusts supplying oral anticancer medicines to external organisations who will take responsibility for administering the medicines, e.g. nursing homes, prisons, children’s homes must ensure that the
medicines are labelled as above and the external organisation has access to the specified regimen protocols.

- Prescribers are responsible for ensuring pharmacies supplying the medicines know the medicines will be administered in an external organisation.

5.1.9. Patient information/counselling

When pharmacy staff and other healthcare professionals supply the oral anticancer medicine to the patient (or relative or carer) they must ensure that the person receiving the medicines fully understands how and when to take their medicines.

The member of pharmacy staff handing the drugs to the patient must also ensure the patient understands:

- what to do in the event of missing one or more doses
- what to do in case of vomiting after taking a dose
- likely adverse effects and what to do about them
- any need for and how to obtain further supplies
- the role their GP is expected to play in their treatment
- The need to inform their health care team if they are taking any over the counter medications/ supplements.
- principles of safe handling, storage and disposal
- that if used, medicine spoons or measures should be used only for the purpose of administering the specific anticancer medicine, washed with warm soapy water after use and disposed of safely when no longer required.
- any drug specific advice regarding safely crushing of tablets or opening of capsules.

It is recognised that, in practice, most of the information may be provided by the consultant/ specialist nurse in clinic or by the pharmacist on the oncology ward. If the patient is not provided with this advice in clinic or on the ward pharmacy staff responsible for cancer services must ensure that systems are in place to provide the advice at the point of dispensing.

- Oral anticancer patients must be able to access the same 24 hour telephone advice service provided for IV chemotherapy patients.
- Patients must be provided with a patient held record document
- The patient’s ‘key worker’ must be identified to the patient
- Trusts must consider what action to be taken if after counselling the patient on their medication it becomes apparent that the patient does not understand how to take the medicines or will have difficulty in compliance.

Trusts must consider what action to be taken if after counselling the patient on their medication it becomes apparent that the patient does not understand how to take the medicines or will have difficulty in compliance. Some patients will benefit from community nurse support and proactive telephone monitoring which may be co-ordinated by the chemotherapy nursing service.

5.2. PRIMARY CARE

The dispensing of oral anticancer agents in primary care is unusual, as described above (section 4.2) there should be no prescribing of SACT in primary care. Prescribing for supply by community pharmacies should be under the care of the oncologist in secondary care. Community Pharmacists should have copies of or access to the written protocols for each patients protocol and treatment plan from the initiating hospital. They should have contact details for an oncology pharmacist at the initiating hospital. Before dispensing such drugs the community pharmacist should ensure that they are able to confirm the following:

- The prescribed dose is appropriate for the patient
- The patient is aware of the monitoring arrangements

Compliance: 100% of patients

5.2.1. Dispensary Standards

- The pharmacist must ensure the directions on the prescription are clear and unambiguous and include, where relevant, the intended period of treatment, including start and stop dates.
• The exact quantity of tablets/capsules required must be supplied. Where pack sizes or splitting or opening packs is likely to affect the integrity of the medication the pharmacist should contact the prescriber for clarification. Where an overage is supplied the pharmacist must ensure that the patient or carer is fully informed of how many tablets will be left and the exact stop date.
• The quantity must be physically checked by counting the number of number of tablets/capsules.
• A different member of staff should final check the prescription from the member of staff who dispensed the prescription.
• All patients must receive a manufacturer's Patient Information Leaflet, with their oral anticancer medicines.
• Pharmacy staff must not break or crush tablets, capsules must not be opened. Queries about difficulties in taking the oral form should be directed to a specialist pharmacist. Use of a suspension or solution is preferred and a suitable preparation must be obtained from an NHS hospital pharmacy or commercial compounding/manufacturing facility with appropriate safe-handling facilities. It must be noted that in many cases there are no liquid alternatives, in these cases refer back to original prescriber.
• Use of compliance aids is not routinely recommended. If there is thought to be a need a risk assessment must be undertaken.
• Label directions must be clear and unambiguous and include where relevant; the intended period of treatment; start and stop dates or the number of days expressed as ‘for X days ONLY’ to indicate that the medicine is not continuous (for short term or intermittent treatment); an appropriate indication of the need for safe handling. Any ambiguities must be referred back to the prescriber.

5.2.2. Patient information/counselling
When pharmacy staff and other healthcare professionals supply the oral anticancer medicine to the patient (or relative or carer) they must ensure that the person receiving the medicines fully understands how and when to take their medicines.
The member of pharmacy staff handing the drugs to the patient must also ensure the patient understands:
• what to do in the event of missing one or more doses
• what to do in case of vomiting after taking a dose
• likely adverse effects and what to do about them
• The need to inform their health care team if they are taking any over the counter medications/supplements.
• principles of safe handling, storage and disposal
• that if used, medicine spoons or measures should be used only for the purpose of administering the specific anticancer medicine, washed with warm soapy water after use and disposed of safely when no longer required.
• any drug specific advice regarding safely crushing of tablets or opening of capsules.

Compliance: Examine Pharmacy procedures.
6. STANDARDS FOR ADMINISTRATION AND HANDLING OF ORAL ANTICANCER MEDICINES

6.1. SECONDARY CARE

The administration of oral anticancer medicines on Trust premises must be carried out and monitored to the same standards as those for parenteral (IV) chemotherapy.

6.1.1 Responsibility for Administration

♦ Administration of oral anticancer medicines on Trust premises on oncology/haematology wards must be undertaken by appropriately qualified clinical staff who have been assessed as competent to follow the same safeguards and checks as when administering IV anticancer medicines.

♦ Clinical staff administering oral anticancer medicines on non oncology/haematology wards to inpatients must contact members of the patient’s specialist team for information and advice about the oral anticancer medicine.

♦ Trusts’ administration of medicines policies must be complied with.

♦ Staff administering oral anticancer medicines must have access to the specified regimen protocols.

♦ When patients are self-administering their oral anticancer medicines, the nurse must take responsibility for the initial and continued assessment of patients who are self-administering. The nurse must have continuing responsibility for recognising and acting upon changes in the patient’s condition with regards to safety of the patient and others on the ward.

♦ With their own consent, if the initial and ongoing assessments have been carried out appropriately and all relevant documentation is completed, patients share the responsibility for their actions relating to the self-administration of their medicines.

♦ Whilst the nurse has a duty of care towards all patients the nurse is not liable if a patient makes a mistake self-administering as long as the assessment was completed according to Trust policy and appropriate actions were taken to prevent re-occurrence of the incident.

6.1.2 Pre Treatment Review

Before oral anticancer medicines are administered on Trust premises the patient must be clinically reviewed by a clinical staff member who will:

♦ ensure that the patient’s medical condition and blood parameters support ongoing treatment.

♦ check results of all investigations, blood parameters and specific drug calculations specified within the treatment protocol/local guidelines.

♦ document the administration of the medicine(s) in the patient’s healthcare record and patient held records, as appropriate.

♦ In the case of inpatients receiving their medications over a period of days the above checks must be done before the first dose is given in hospital and then regularly during treatment according to the parameters specified in the written protocol, unless their clinical condition indicates otherwise.

♦ If any changes are required, patient record must be updated, and patient informed especially if they are self-administering.

6.1.3 Waste disposal

Standards for waste disposal of systemic cancer therapy are described in the SELCN Service Specification and individual Trust policies for the disposal of medicinal waste. These standards and policies apply equally to oral anticancer medicines.

Patients must be given advice on how to safely store their oral anticancer medicines and told where and how to return unused medicines for disposal.

6.1.4 Standards for Governance, Quality and Risk Management and compliance criteria

Quality Standards and Clinical Governance of systemic cancer therapy are described in the SELCN Service Specification and apply equally to oral anticancer medicines.
6.2 PRIMARY CARE

6.2.1 Waste disposal
Pharmacists and pharmacy staff must be familiar with procedures for safe handling of cytotoxic medicines and disposal of waste. The RPSGB gives guidance on how to manage cytotoxic waste in Community Pharmacy http://www.rpsgb.org/pdfs/hazwastecommphguid.pdf

Patients must be given advice on how to safely store their oral anticancer medicines and told where and how to return unused medicines for disposal.
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