B15/S/a

2013/14 NHS STANDARD CONTRACT
FOR CANCER: CHEMOTHERAPY (ADULT)

SECTION B PART 1 - SERVICE SPECIFICATIONS

Service Specification No.	B15/S/a
Service	Cancer: Chemotherapy (Adult)
Commissioner Lead	
Provider Lead	
Period	12 Months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

National Context

Systemic anticancer therapy is for the treatment of solid tumours AND haematological cancers through the systemic delivery of agents that have antitumour effects. Chemotherapy refers to any systemic anti-cancer therapy, this includes monoclonal antibodies/targeted therapies, intravenous, subcutaneous, intrathecal and oral chemotherapy as well as topical treatments for bladder cancer; hormonal treatment is excluded. This service specification is for the treatment of adults requiring systemic anticancer therapy (i.e. not topical bladder treatment) as part of their treatment for their cancer care management.

The Improving Outcomes Guidance (IOG) developed by NICE (http://guidance.nice.org.uk/CSG) refers to delivery of best practice treatments and support for patients through multi-disciplinary team working.

The Improving Outcomes: A Strategy for Cancer (2011) sets out in section 6 (Improving outcomes for cancer patients: better treatment) that “ensuring that all cancer patients receive the appropriate treatment, delivered to a high standard, is critical to improving cancer outcomes. The right treatment can also be the most cost effective treatment”. It also states that “there is evidence that the UK is a relatively low user of some cancer drugs and that patients may be treated more conservatively than in other countries.”

A report from the National Chemotherapy Advisory Group (NCAG) in August 2009 highlighted that the use of chemotherapy has expanded markedly in recent years, with an increase of around 60 per cent in the amount of chemotherapy delivered over a four year period. Chemotherapy has brought undoubted benefits to many thousands of patients. However, the three reports below identified serious concerns about the quality and safety of service delivery, therefore the focus of the NCAG report in 2009 was entirely on safety and quality:

- The national overview of the peer review appraisals undertaken between 2004 and 2007 showed that only around one half of chemotherapy services had cancer network-wide lists of agreed acceptable regimens and guidelines/protocols for chemotherapy service delivery.
- The National Patient Safety Agency (NPSA) issued a Rapid Response Alert in 2008 on oral chemotherapy following a significant number of safety incidents.
- The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) analysed the care given to patients who received systemic anticancer therapy in June and July 2006 and who died within 30 days of treatment.
- During 2010 the Department of Health (DH) published a further document, Chemotherapy Services in the Community, as guidance for PCTs and their cancer networks on the potential to develop chemotherapy services in the community. Further details will be provided about 'Extending Patient Choice of setting' in section 2.6

Local Context

This adult chemotherapy service specification has been commissioned to expand capacity of chemotherapy services, and to improve access to high quality provision for adult patients who require chemotherapy as part of their planned cancer treatment and support

The service specification is based on the following principles:

- All providers delivering chemotherapy should have formal and defined links to a cancer centre.
- The service should be well integrated and be able to demonstrate effective participation in multi-disciplinary team meetings to ensure well managed transitions between services and across primary, secondary and tertiary care boundaries.
- The service should employ models of care, interventions and treatments that are evidence based.
- The service should demonstrate full exploitation of the existing equipment, workforce knowledge and skills including the development of new roles for all health professionals, where appropriate.
- The service should use technology, audit, data management and analysis, service reviews, intelligence and other techniques to evaluate its effectiveness and to drive continuous service improvement.

- All new treatments should be assessed prior to their introduction to ensure that they are incorporated into treatment algorithms and fit with strategic plans developed by clinicians, commissioners and networks.
- There must be a robust system of clinical governance in place and all staff must be fully familiar with the treatments employed within the service and be trained and deemed competent to deliver them as per their role.
- Every relevant and appropriate person involved within the service should be active participants in the working groups of their cancer or integrated network(s) and be involved in the development of policies and guidance and should work in accordance with them.
- Service improvement should be shaped by service user and carer involvement.
- Equity of access and quality of care should be provided to all who need it regardless of sex, age, gender or ethnicity unless there is robust evidence that these factors affect the effectiveness of the intervention/treatment
- All new patients receiving chemotherapy must have been discussed by an appropriate cancer centre or cancer unit multi-disciplinary team (MDT) before being accepted for treatment.
- Multidisciplinary teams have the core attendance and right patient data (e.g. relevant test results) to optimise evidence-based treatment decisions
- There must be arrangements in place for urgent chemotherapy treatment prior to multidisciplinary team discussion
- All patient treatment plans must be supervised by a multidisciplinary team member with the appropriate competencies.
- Active promotion of education and self-management for people with cancer should be undertaken at every opportunity.
- The service should be actively working towards personalising treatment, with service flexibility to match the individual's needs and those of their carers.
- Patients should receive the right treatment, at the right time, in the right place, which, where possible, will be as close to home as practicable.
- Patients (and carers) must receive clear written guidance when consenting to treatment to include the treatment intent, prognosis and potential complications associated with their treatment with clear instructions who to contact if they need advice outside working hours and how to proceed in the event of a medical emergency.

In order to demonstrate the effective organisation of chemotherapy services a number of national requirements will need to be met by providers including:

Clinical governance

Good clinical governance systems and policies must be in place and integrated into organisational governance with clear lines of accountability and responsibility for all clinical governance functions.

Clinical quality

Quality assurance systems must be in place and approved by the commissioning body with regular reporting of outcomes. Providers must provide a report on the quality of the chemotherapy service at least once a year and make this public.

Compliance with:

- Cancer Peer Review measures for clinical chemotherapy and oncology pharmacy services
- Systemic cancer therapy access targets
- NICE guidance on anti-cancer medicines
- DH guidance on intrathecal treatments
- Cancer peer review measures for Acute Oncology Services

Data and information management

The provider should have an explicit data and information strategy in place that covers

- Types of data
- Quality of data
- Data protection and confidentiality
- Accessibility
- Transparency
- Analysis of data and information
- Use of data and information
- Dissemination of data and information
- Risks

The provider should have an electronic prescribing for chemotherapy.

The provider must ensure completion and upload of the mandated Systemic Anti-Cancer Therapy (SACT) dataset. There are 8 fields that are mandated and every Trust should be uploading this data already. All 42 fields should be uploaded by April 2014.

Implemented chemotherapy Care Pathways

The provider should implement clear chemotherapy care pathways and the actions that need to be taken by commissioners and providers to ensure high quality care.

Many cancer patients will require urgent support at some point, either as a result of their disease progressing or because of complications with their treatment. Acute oncology services as recommended by the National Chemotherapy Advisory Group (NCAG) and now a central part of the Manual for Cancer Services will play a critical role in managing urgent care from complications of treatment when a cancer patient needs it. Every hospital with an A&E should have an acute oncology service and every provider treating cancer patients should establish links with one or more as appropriate.

Cancer Drugs Fund

On 27 July 2010, the Department of Health announced plans to establish a Cancer Drugs Fund from April 2011, as a means of improving access to cancer

drugs prior to the proposed reform of arrangements for value-based branded drug pricing from 2014. Providers are also expected to submit data for the CDF dataset/national audit.

The funds will be accessed via NHS England and supported by 4 designated Local Area Teams. This will give access to those drugs not approved by NICE on the basis of cost effectiveness, clinical outcomes and not commissioned through local agreements but which are deemed by local clinicians to be clinically effective and safe for patients meeting the agreed clinical criteria:

- Drugs which have yet to be appraised by NICE;
- Drugs which will not be considered by NICE due to the small patient population for which they are licensed, but which are not covered by specialised commissioning arrangements;
- Drugs which have not been recommended by NICE, mainly on the grounds of cost effectiveness; and
- Drugs which cannot be appraised by NICE, as clinicians wish to use them outside their licensed indication to treat forms of cancer with a similar biology of disease to that for which they are licensed (off-label treatment).

Providers are expected to provide data for the CDF audit.

All decisions must consider:

- Promoting fairness and consistency in decision making and reduce the potential for inequity
- Providing a means of expressing the reasons behind the decisions made.
- Reducing risk of judicial review by implementation of robust decision- making processes that are based on evidence of clinical and cost effectiveness and an ethical framework

Guidance on the CDF has been published separately and will be revised again during 2013/14 to take into account the future of the fund.

Clinical trials

Treatment on a clinical trial is regarded as a gold standard of care. Clinical trials are vital for improving treatment for people with cancer and adults with cancer should be enrolled into and treated on a clinical trial, where a clinical trial for their particular cancer is available.

2. Scope

2.1 Aims and objectives of service

The aim of the chemotherapy service is to ensure the provision of the safe delivery

of chemotherapy drugs, and consistent quality care for patients who are diagnosed with cancer, maintaining high standards of care, access to chemotherapy treatment irrespective of geographical location, equitable patient centred access and treatment for all, and in line with national standards and requirements.

The appropriate delivery of adult chemotherapy to patients with cancer will ensure

that the outcomes from treatment will meet the requirements of the five domains of the NHS Outcomes Framework:

- Domain 1 – preventing people from dying early – by delivering evidence based protocols maximising the potential for cure and 5 year survival.
- Domain 2 – enhancing quality of life for people with Long Term Conditions (LTCs) – where cure is not a viable outcome ensuring best possible. quality of life through, where appropriate, delivery of palliative chemotherapy
- Domain 3 –helping people recover from episodes of ill health.
- Domain 4 –ensuring that people have a positive experience of care.
- Domain 5 – treating and caring for people in a safe environment.

The pathway of care for any chemotherapy patient will include the following objectives that providers will be required to deliver:

- Patients will be discussed by a multidisciplinary team at diagnosis and before the patient receives their first treatment.
- There will be specialist oncology input which is essential for initiating, prescribing of chemotherapy and developing the treatment plan.
- Access to specialist oncology is required for assessment during treatment and at relapse,
- An electronic prescribing system will be in use for chemotherapy according to evidence based protocols.
- The provider service will need to ensure sufficient oncology pharmacists and technical pharmacy staff for the checking of prescriptions, reconstitution and delivery of drugs.

Chemotherapy trained nurses/oncology pharmacists will be available to ensure patients receive adequate information and education before a course of chemotherapy begins, to assess symptoms and coping prior to every cycle, and safely deliver the treatment. Their role is important in providing information and support while treatment is on-going including education on signs and symptom management/early alerts.

- The service should ensure that there are good communication arrangements between oncologists, chemotherapy nurses and aseptic services/pharmacy services
- A patient held record will be given to patients of their current chemotherapy treatment which is up dated at each visit.
- The provider will need to offer patients the choice to receive their treatment in different locations as is appropriate for their clinical status. This will need to

be supported by patient information and protocols to support patients.

- The treatment environment is required to be fit for purpose and provide adequate privacy for patients. Health Building notices are available for this area if a new build is planned.
- The service will need to ensure that there is provision of a 24 hour telephone lines for advice by staff who have been trained to manage these calls and/or part of the Acute Oncology service.
- Providers will need to ensure that patients are aware of how to access out of hours services (24 hours a day, 7 days a week), how to contact this service and access to emergency care should admission with toxicity following chemotherapy occur.
- Good communication systems between teams so that admission of a patient with toxicity or disease progression is known about by the appropriate team in a timely fashion.
- Services will need to ensure access to oncologist/haematologist advice as they actively support chemotherapy patients with neutropenic sepsis within acute trusts.
- Access to site specific specialist nurses, counselling, dietetics, other allied health professionals for support when required.
- Discharge and follow up care should be clearly agreed and implemented, and end of treatment summaries developed.
- There should be communication with primary care practitioner at the outset of treatment,
  during any significant change to treatment and at the end of treatment.
- There should be timely treatment with delivery of waiting time targets.
- Each service will be required to adhere to National cancer peer review programmes; Manual for Cancer Services: Chemotherapy Measures
- If palliative chemotherapy is being offered then services need to ensure that there is access to specialist care colleagues.

2.2 Service description/care pathway

The service outlined in this specification is for adults with cancer requiring specialised chemotherapy treatment, whether curative or palliative, as part of their planned cancer treatment and support, outlined within this specification.

The contracting framework for adult systemic cancer therapy services describes adult systemic cancer therapy as encompassing all types of treatments for patients who require chemotherapy or immunotherapy delivered by the parenteral (including intrathecal, sub cutaneous) or oral route. This specification covers both solid tumour oncology and haemato- oncology services.

The NCAG report describes the chemotherapy pathway as being an initial referral to an oncologist/haemato-oncologist and ending with completion of treatment and development of a subsequent care plan

This chemotherapy service comprises of the following elements:

- Entry to the pathway/ service and initial assessment
- Access and referral to an oncologist/haemato-oncologist
- Assessment and decision to treat
- Point of intervention
- Prescribing first cycle
- Prescribing subsequent cycles
- Delivery and treatment environment
- Patient and carer information, education support and advice
- Urgent assessment and management of complications
- Preparation of chemotherapy
- Dispensing and reconstitution
- Delivery / administration
- Management of complications
- After treatment:
  - End of treatment record and subsequent care plan

Entry to the pathway/service and initial assessment

New patients must be discussed by a multidisciplinary team at diagnosis and before the patient receives their first treatment.

Referrals for chemotherapy are made to a consultant medical or clinical oncologist or haemato-oncologist who is a member of that multidisciplinary team and new patients on a chemotherapy pathway should have been discussed at an appropriate multidisciplinary team

Holistic assessment of the patient needs and pre-treatment tests must be carried out and reviewed prior to each cycle of chemotherapy and any abnormality / identification of need acted upon appropriately. This should include:

- Conducting a comprehensive assessment of the patients physical, social, psychological, emotional and spiritual needs
- Nutritional assessment, weight and height
- Conducting baseline clinical observations
- Identifying co-morbid conditions that may impact on treatment
- Noting any past medical history including allergies
- Noting medication record
- Assessing WHO performance status and overall fitness for treatment
- Assessing venous access as appropriate and discuss options i.e. Central Venous Access Devices and make appointments for insertion as necessary

The patient must be pre-assessed by the oncologist or chemotherapy nurse. The oncologist and chemotherapy nurse must assess using patient suitability criteria, regimen selection, patient choice, prior to obtaining consent.

- Patients will be given ample opportunity to ask questions.

Patient must be given verbal and written information regarding treatment and support available (clinical nurse specialist, social worker, out of hour's advice line, district nurse etc.)

Consent forms must be signed. An informed consent checklist completedand reconfirmation of the patient's compliance to treatment and receipt of generic written information.

Arrangements will need to be available for patients with learning difficulties and for those patients for whom English isn't a first language.

The provider must have systems and processes in place between organisations

and these services should have service level agreements (SLAs) between organisations, in order to ensure all parties are clear who holds responsibility for which part of the pathway in place to:

- Register patients
- Collect relevant clinical and administrative data
- Manage the appointment process, (reappointment and DNA process, if appropriate)
- Provide information to patients
- Undertake initial assessment in the appropriate location.

Point of intervention

Systems will be in place to ensure the patient receives timely treatment with delivery of waiting time targets.

The consultant oncologist /haemato-oncologist is responsible for initiating prescribing of the chemotherapy and developing the treatment plan.

Access to specialist oncology is required for assessment during treatment and at relapse.

Chemotherapy for adults is normally provided on an outpatient (OP)/ day patient basis but patients may be admitted due to their overall condition, concurrent radiotherapy or co-morbidities rather than as a result of their chemotherapy delivery alone.

While patients are currently receiving treatment they will be supported by the chemotherapy clinical team. During treatment patients contact with the wider cancer multidisciplinary team (clinical nurse specialist, dietitian etc.) should be maintained and encouraged. Registered nurse/pharmacist should review in-patients whilst chemotherapy treatment is on-going. For outpatient treatment, reviews must be in line with the protocol for the regime.

Patients during chemotherapy must be given access to 24 hour helpline (24 hours a

day, seven days a week) for urgent advice about side effects or symptoms of infection from chemotherapy. The helpline must be answered by chemotherapy trained nurses who will be able to give advice. Those giving the advice should have access at least to basic information about a patient's condition and treatment. They should also actively manage the pathway of care if an acute assessment is required. Processes should be in place to track / follow up any actions that occur following the call. This should be subject to regular audit of the effectiveness of the advice. Telephone advice and triage services should operate at least to the standards described in the UKONS NHS 24 hour helpline brochure(http://www.ukons.org/docs/24%20evaluation.pdf)

Patients receiving treatment through the outreach service must be able to access the same wide range of expert help as patients receiving chemotherapy at an acute hospital chemotherapy unit i.e. from the multidisciplinary team including oncologist, tumour specific specialist nurses, chemotherapy nurses, dietetic support and other required therapies.

It is essential that an individual consultant retains the responsibility for overall patient care across the whole pathway and will provide care when a patient is receiving treatment in a different setting/service and retains overall responsibility for the management of side effects and complications. A consultant practitioner (such as an appropriately trained and identified registered pharmacist or nurse at consultant level) may provide the link between the chemotherapy service and the multi-disciplinary team.

The service itself will also have clinical oversight and accountability for governance purposes. There must be a professional head of the chemotherapy service directly responsible for the development, management and ultimate clinical accountability and responsibility for the service.

Chemotherapy treatment should be commenced during normal hours (usually 8-6 Mon-Fri) wherever possible when support services and expert advice are available.

Patients receiving chemotherapy treatment must have direct access to appropriate inpatient care fully equipped to deal with the side effects and acute complications of the treatment, including access to out-of-hours specialist oncologist advice, and management of emergencies, in accordance with clinically managed network guidelines.

The chemotherapy service forms part of the pathway of cancer care for patients and it has been developed with formal links to the relevant multi- disciplinary teams in mind. Chemotherapy pathways must be reviewed formally on a regular basis and also adhere to the local network guidelines. User and carer involvement is an important step in this process.

If any of the chemotherapy activity is sub-contracted to another provider (e.g. satellite departments, paediatric oncology shared care units, community teams or external contractor) there must be clear and formal accountability processes and structures in place to ensure continuity of clinical care that is safe and effective. There also a need

for there to be a clear mechanism for ensuring treatment information on the patient is captured and provided back to the accountable trust, and that all work processes are protocol led and clearly defined both within the provider and with any other service provider. Any deviation from these protocols will be clearly documented and investigated with regular reviews, and where appropriate updated.

Before subsequent cycles of chemotherapy the following must be discussed and documented:

- Patients experience of the previous treatment, side effects and concerns
- Psychological, social and spiritual needs and advice must be assessed
- Physical toxicities using the WHO toxicity score assessed
- Blood results, ensuring that they are within the agreed parameters to continue with treatment assessed
- Weight recorded, BSA calculated, performance status to ensure no dose modifications are required

The provider must have systems and processes in place at point of intervention to ensure that:

- The intervention is conducted safely and in accordance with accepted quality standards and good clinical practice.
- The patient receives appropriate care during the intervention(s), including on treatment review and support, in accordance with best clinical practice
- Where clinical emergencies or complications do occur they are managed in accordance with best clinical practice
- The intervention is carried out in a facility which provides a safe environment of care and minimises risk to patients, staff and visitors
- The intervention is undertaken by staff with the necessary qualifications, skills, experience and competence
- There are arrangements for the management of out of hours care according to best clinical practice
- There is regular communication with primary care
- Completion and upload of the mandated Systemic Anti-Cancer Therapy (SACT) Dataset, to include the recording of Performance Status prior to each cycle of chemotherapy. The standard covers all patients receiving cancer chemotherapy in or funded by the NHS in England.
- All providers should ensure effective scheduling and that appropriate scheduling tools are used to ensure patient choice and improved access to services in order to maximise efficiency

Preparation of Chemotherapy

Chemotherapy must be delivered as safely as possible i.e. it must conform to the Manual for Cancer Services: chemotherapy measures (2011); and, national standards set following NPSA (National Patient Safety Agency) oral and vinca-alkaloid alerts (2008);NCEPOD report (2008) and NCAG report (2009)

recommendations.

Each clinical chemotherapy service must have a policy detailing the safe reconstitution of cytotoxic drugs. The following are the principles and guidelines upon which the local policy should be based. Manipulating and reconstituting cytotoxics poses the greatest risk. For this reason, cytotoxics should only be reconstituted in an accredited and regulated/audited pharmacy aseptic unit by appropriately trained and experienced staff. Any staff responsible for reconstituting cytotoxic drugs must have undergone training in line with:

- 1988 Health and Safety Commission approved Code of Practice entitled "The Control of Substance Hazardous to Health" (COSHH).
- Aseptic dispensing for NHS patients: a guidance document for pharmacists in the United Kingdom by Farwell, John .Great Britain. Department of Health,1993
- Rules and Guidance for Pharmaceutical Manufacturers and Distributors - MRHA 2007 - the 'Orange Guide'. 'http://www.mhra.gov.uk/Publications/Regulatoryguidance/Medicines/CON2030291
- Quality Assurance of Aseptic Preparation Services 2005 Alison M. Beaney

Local arrangements should be in place to ensure that as far as practicable high cost items are only reconstituted after patient's blood results are known. All cytotoxic drugs should be prepared in accordance with locally approved policies and protocols.

Delivery of treatment

The vast majority of all intravenous chemotherapy treatments are delivered in dedicated day case units. Providers will want to ensure that they have maximised the use of regimens being delivered as a day case, rather than treatments being administered as an inpatient.

Inpatient delivery of chemotherapy should be kept to a minimum by:

- Maximising the use of oral medicines
- Using central lines for delivering prolonged infusions
- Developing nurse and/or pharmacy led services
- Extending opening hours of services
- Developing of site closer to home settings

Treatment should be available in settings where staff are appropriately trained to ensure maximum patient safety, and in well designed facilities.

After treatment

Patients will be given appropriate after treatment care and follow-up including information on post treatment reactions to expect and with advice on self

management.

Patients should be given contact details of the service to support post treatment reactions and anxieties.

Following chemotherapy the responsible clinician should confirm to both the patients GP and referring clinician what treatment has been delivered, the patient's condition and any post treatment arrangements.

There should be end of treatment protocols in place for patients who have completed their treatment with the right guidance and advice on 'how to live' after chemotherapy as well as protocols for patients who have been unable to complete treatment.

Where and if appropriate,links to primary care should be established and GPs should be informed if patients are suitable to be considered to be added to the locality end of life care register/electronic pallitive care coordination system (EPaCCS).

Discharge letters must go to the clinician continuing the patient's care – e.g. the GPs or other clinician and a copy placed within the notes. Copies of these should be provided for the patient unless they do not wish to have them.

The patient will receive a treatment summary and care plan

The provider must have systems and processes in place at the pathway exit, which are agreed with all parties and networks to:

- Undertake telephone triage for advice to patients having chemotherapy
- Make urgent onward referrals where life-threatening conditions or serious unexpected event occur during an intervention/assessment
- Ensure that patients receive discharge information relevant to their intervention including arrangements for contacting the provider and follow up if required
- Provide timely feedback to the referrer re intervention, complications and proposed follow up
- Ensure that the patient receives required drugs/dressings/aids
- Ensure that support is in place with other care agencies as appropriate
- Ensure completion and upload of the Mandated Systemic Anti-Cancer Therapy(SACT) Dataset.

Service model Solid Tumour Oncology and Haemato-oncology

The solid tumour oncology service will usually work within a network model of services and operate as a hub and spoke of the Oncology Centre. There are a number of different service models agreed across Networks.

The haematology chemotherapy service will be based at the specified sites.

Hospitals will provide a service for patients at the main treatment centre and in other sites as agreed with the network or lead commissioner. Different models may be

operating and the services/sites will need to be agreed as above.

Which regimens are given within a specific location / unit will be agreed by the provider and commissioner of the service.

The service will consist of the provision of chemotherapy by a clinical team using appropriate equipment in the right facilities supported by medical / clinical oncology or by haemato-oncologist staff. It is essential that a consultant clinical / medical oncologist or consultant haemato-oncologist retains the responsibility for overall patient care across the whole pathway and will provide care wherever the patient is treated, including homecare, and retains overall responsibility for the management of side effects and complications. A nurse practitioner may provide the link between the chemotherapy service and the multi-disciplinary team. However, when a patient is undergoing other types of treatment in their cancer pathway e.g. surgery or end of life, other specialist consultants will have the responsibility until the patient requires further chemotherapy.

Cover arrangements must be in place for absence and holidays, out of hours and emergencies to ensure continuity of service, and may include links with the oncology centre. All out of hours arrangements should be provided by trained staff only.

As part of the chemotherapy service and in line with the key recommendation for an Acute Oncology Service (NCAG 2009) all hospitals with emergency departments should establish an Acute Oncology Service, which encompasses:

- Management of patients with severe complications following chemotherapy or as a consequence of their previously diagnosed cancer.
- Management of patients who present as emergencies with previously undiagnosed cancer.
- Bring together expertise from oncology disciplines, emergency medicine, and general medicine and general surgery.
- Protocols for the management of oncological emergencies and training for A&E staff.
- Training for physicians – on management of acutely unwell cancer patients.
- Access to information on individual patients across the clinical network.
- Early review by an oncologist or oncology nurse specialist (within 24 hours).
- AOS to have 24/7 access to telephone advice from an oncologist
- Fast track clinic access from A&E

The principle of having an AOS is about optimising high quality care for patients as well as admission avoidance and should bring together relevant staff from A&E, general medicine, haematology and clinical/medical oncology, oncology nursing, palliative care and oncology pharmacy. This will provide emergency care not only for cancer patients who develop complications following chemotherapy, but also for patients admitted with progressive disease. All members of the team must have

access to chemotherapy related patient information, in real time, in order to ensure the individual patients treatment plan is taken into account when managing symptoms and toxicities, and that any toxicity management treatment received is documented in the patient's healthcare record. Continuity of data may be maintained through electronic systems or as patient hand held records.

All providers should ensure that all cancer patients and their carers have access to high quality patient information which is tailored to their needs and available at key stages of their patient journey. This should be in the form of an Information Prescription (IP).

An Information Prescription (IP) provides personalised health and medical information about a patient's diagnosis, treatment and care plan. It should broadly cover the key points in the discussions they've had with their doctor, nurse or other health carer. Information prescriptions have been developed by the NHS in England to improve information given to people with cancer. The public can access the Information Prescription Service directly through NHS Choices. http://www.nhs.uk/ipg/pages/ipstart.aspx

Care pathway service

All providers are required to follow the national generic chemotherapy pathway and locally customised developed pathways, and to set up planned audit against the pathway. Outcomes (including morbidity and mortality, waiting times) will be monitored as a minimum as part of the quarterly contract quality review or as locally agreed.

*(Please refer to pathway on **Annex 1**)*

Where local pathways exist for solid tumour oncology they should be designed to show clearly the links with the oncology centre, including how a patient enters, is managed and discharged from the service. Reference should be made to the roles and responsibilities of the provider and local clinical network and how the chemotherapy pathway is aligned within the overall cancer pathway.

All pathways should include timelines and alert mechanisms for potential breaches (i.e. cancer waiting times), audit processes to ensure standards are met, and specification of provider and commissioner responsibilities. The provider(s) should meet standards for prescribing, adhere to the required competency checks and should foster a responsive and participative approach to including patients' views about their care in the design of care pathways, and should collaborate with other organisations involved in the patient pathway to provide a seamless patient journey.

Where chemotherapy is delivered in the community providers should adhere to local pathways and policies in line with local Network policies. The oncology pharmacywill prepare the chemotherapy in the same way that they would at the main oncology centre. The chemotherapy will then be transported safely to the patient.

Where private third party providers are used, they may deliver the chemotherapy directly to the community setting. In some systems, this will involve the nurse collecting the chemotherapy from a central dispensary/store and with other models, the chemotherapy may be delivered by courier, scheduled to arrive at the planned administration time. All NCAG recommendations relating to the recording and delivery of chemotherapy prescriptions apply whatever the delivery setting. It should be noted that where pharmacy services are outsourced training of staff must be ensured, and prescribing, clinical checks and record keeping aspects of the services remain within the NHS. In line with MHRA guidance, in order to supply aseptically dispensed medicines to patients 'outside' the acute Trust setting, this can only be done if the pharmacy aseptic preparation facility holds an MHRA licence for this activity.

2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

* - Note: for the purposes of commissioning health services, this EXCLUDES

patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

This specification covers chemotherapy for adults that require chemotherapy as part of the treatment for their cancer care management. Those who are 17 years old with adult tumours will be considered for the service based on their preference and the distance they live from an adolescent centre.

2.4 Any acceptance and exclusion criteria

Acceptance Criteria

Referrals for chemotherapy are made to a consultant medical oncologist, clinical oncologist or haemato-oncologist who are members of the multidisciplinary team. Patients on a chemotherapy pathway must have been discussed at an appropriate multidisciplinary team.

The service will accept referrals for patients who have been assessed as suitable for chemotherapy.

There should be official documentation or a referral form for any of the tumour sites to use when requesting chemotherapy.

Exclusion Criteria

Management of chemotherapy in children and young adults treated within the children's services – see separate service specification.

2.5 Interdependencies with other services

Co-located services.

The service should be part of a clinical managed network and there should be significant representation from the local service on the network chemotherapy group. The service should work closely with its local, regional and national colleagues to ensure continuous quality improvement.

Additionally, with the advancement of technologies for cancers, there is now a clear need to have access to the appropriate histology and where relevant biomarker analyses when developing treatment plans for patients. If the commissioning outcomes framework includes indicators around availability of these types of information at multidisciplinary team then this will ensure that the right patient receives the right therapy and therefore, cost-effective use of interventions (again as denoted by for example, NICE guidance).

Chemotherapy treatment is part of an overall cancer management and treatment pathway. Decisions on the overall treatment plan must relate back to a multidisciplinary team discussion and decision. All oncologists and haemato-oncologists will be expected to meet the requirement for attendance at their appropriate site-specific multidisciplinary teams.

Interdependent services

The adult solid tumour oncology service will operate as a hub and spoke service and will be required to set up and maintain formal links from the cancer centre to the local district general hospitals and to include governance, training and development and networked e-prescribing technology, and cross-cover arrangements for medical staff, where locally agreed.

Most aspects of the haematological chemotherapy services will be covered by district general hospitals except some specialist services, for example blood and marrow transplantation(BMT), although some simpler elements of the BMT pathway may be delivered locally. Commissioners and providers need to be clear in relation to the funding streams (specialist commissioning or otherwise) where some elements of the pathway are not delivered in specialist centres. Providers and commissioners should consult guidelines on the levels of care relating to the provision of facilities for patients with haematological malignancies.

Chemotherapy services will have a relationship with: diagnostics, specialist pathology services, pre-operative assessment; enhanced recovery; clinical

psychology, general medicine, basic biomedical research and clinical research.

Related services

- Counselling services.
- Macmillan nurses, community nurses and social workers.
- Appropriate support groups
- Patient Advice and Liaison Service (PALS).
- Primary care
- Social care services

2.6 Patient choice and chemotherapy treatment in different clinical settings

It is important that chemotherapy patients are actively consulted on their choice of therapy and of where this is delivered. Liberating the NHS: An Information Revolution and The power of information: putting all of us in control of the health and care information we need (Department of Health 21 May 2012) makes it clear that:

- Patients must have the information they need to make the right choices about their health and treatment
- The NHS and social care must have the information they need, appropriately analysed by inequality/equality group, to enable them to make the right decisions around commissioning and providing quality services;
- The public must have the information they need to make the right choices about healthy lifestyles.

Liberating the NHS: greater choice and control, is based on patients being at the heart of decision-making in the NHS. No decision about me without me should be a guiding principle in the delivery of all treatment. The report envisages a presumption of choice and any qualified provider across the majority of NHS-funded services by 2013/14. In cancer, a range of different forms of choice are relevant, including:

- When to have treatment;
- Where to have treatment (some treatments can be given in hospital or in the community);
- Which organisation delivers treatment and care;
- Which team delivers the treatment;
- What form of clinically appropriate treatment to have (drug and route).

Applying choice across the pathway will be important for cancer as patients may wish to choose different providers for different forms of treatment and care. More and more care is being provided outside of hospital and in many cases within patients' home whether in the form of self-care or a homecare delivery provider. Risk management, clinical governance, safety, adverse events management, carer/healthcare staff education, patient education, and patient experience are

all elements that would need to be quality assured and must meet the minimum standard.

Patient Experience

The service should be patient centred and should respond to patient and carer feedback. Excellent communication between professionals and patients is particularly important and can avoid complaints and improve patient satisfaction. Patient experience is reported in the National Cancer Patient Survey. In this survey patients with a clinical nurse specialist reported much more favourably than those without on a range of items related to information, choice and care therefore chemotherapy patients should have access to a clinical nurse specialist. The national programme for advanced communications skills training provides the opportunity for senior clinicians to improve communications skills and all core multidisciplinary team members who have direct clinical contact with patients should have attended this.

Community Chemotherapy settings

The publication of the 2010 NHS white paper focused the NHS on extending choice for patients and cutting bureaucracy. Extending the choice of chemotherapy service providers from secondary care to include community service providers builds upon previous NHS initiatives.

Many of the chemotherapy treatments for cancer can be safely delivered away from major cancer centres. The National Chemotherapy Advisory Group (NCAG) report, Chemotherapy Services in England: Ensuring Quality and Safety, which reported in August 2009, concluded that each cancer network should consider whether there were opportunities to deliver chemotherapy closer to patients' homes.

The key drivers for delivering chemotherapy services in the community are:

- Improved patient choice
- Improved experience
- Managing the on-going increasing demand for chemotherapy. Key issues that need to be addressed are:
- Use of e-prescribing systems
- Commissioning agreed pathways and specifications
- Clinical governance and leadership

A separate Information Pack has been prepared on 'Extending Choice of Setting'. This was originally developed under the auspices of Any Qualified Provider, but it is now recognised that AQP is not the appropriate vehicle for Community Chemotherapy. The pack can be found on the NCAT website and 'linked' on the AQP/Patient Choices website. This document covers all areas around developing and

increasing the use of community settings whilst responsibility for the management of patients remains under secondary care clinicians.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

National Cancer Peer Review

The Manual for Cancer Services is an integral part of Improving Outcomes: A Strategy for Cancer and aligns with the aims of the coalition government to deliver health outcomes that are amongst the best in the world. The manual will support the National Cancer Peer Review quality assurance programme for cancer services and enable quality improvement both in terms of clinical and patient outcomes.

National quality standards/measures for cancer services were first published in 2001 and were updated in 2004, 2008 and 2011. The range of measures has subsequently been extended to cover virtually all cancer-sites and the current SACT specific measures were released in April 2011. It is intended that the measures will underpin the NICE quality standards relating to cancer.

The service will comply with the National Cancer Peer Review process and endeavour to meet all appropriate measures, with a minimum 80% compliance. Where this is not possible, the service will develop and implement an agreed action plan, this will be agreed by and monitored by the commissioners of the service.

In line with the Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS (5thDecember 2011) the service will require that all NICE Technology Appraisal recommendations are incorporated automatically into relevant local NHS formularies in a planned way that supports safe and clinically appropriate practice.

The provider is required to undertake annual patient surveys and develop and implement an action plan based on the findings. The National Chemotherapy Implementation group (NCIG) along with the Patient Experience Advisory Group (PEAG) have developed a national survey for use by chemotherapy services.

The peer review process requires a patients survey in the last two years.

The provider must conform to national guidance and conduct local audits are to ensure standards are being met.

The provider must be able to offer patient choice. This will be both in the context of appointment time and of treatment options and facilities, including treatments not available locally.

Robust systems must be in place to report deaths within 30 days of chemotherapy:

- Advice from the Coroner's Society of England and Wales reminds all of the clinicians involved in the care of cancer patients who die within 30 days of chemotherapy that patients whose death is caused by or hastened by treatment should be reported to HM Coroner.

The service will comply with the relevant chemotherapy specific sections of the NICE quality standards which define clinical best practice where they are developed.

3.1.1 Mandated Systemic Anti-Cancer Therapy Dataset

Standard Number ISB 1533

In September 2011, the NHS Information Standards Board granted Full Stage approval to the Systemic Anti-Cancer Therapy (SACT) Information Standard. The standard covers all patients receiving cancer chemotherapy in or funded by the NHS in England. The data standard relates to all cancer patients, both adult and paediatric, in acute inpatient, day case, outpatient settings and delivery in the community. It covers chemotherapy treatment for all solid tumour and haematological malignancies, including those in clinical trials.

NHS Trusts providing cancer chemotherapy services in England are required to collect and submit chemotherapy data. The SACT website is operational (www.chemodataset.nhs.uk) where all the relevant documentation, data submission guidance, schedules for submission and FAQs can be found. The website will also provide access to the upload portal for the SACT data submissions. There is also best practice advice from the MHRA and in the BNF (British National Formulary) regarding the prescribing of bio-similar medicines by brand name (as opposed to chemotherapy where generic prescribing is the standard). This would facilitate appropriate reporting and monitoring of safety data on bio-similar SACTs.

Full compliance under this agreement is expected with the mandated SACT dataset and reported with the required format and timelines. All trusts with e-prescribing systems should currently be submitting monthly chemotherapy data to the Chemotherapy Intelligence Unit (CIU) via the upload portal on the website. Those without e-prescribing systems should be uploading at least the mandatory fields (September 2012) and have an action plan and timetable agreed with the CIU for uploading the entire dataset which will be due by April 2014.

4. Key Service Outcomes

See Section B part 8.1 Quality Requirements

Below are draft key service outcomes for the chemotherapy service. These will be developed further by the Chemotherapy Clinical Reference group during 2013/14. It is hoped that much of the data will be available from the SACT dataset.

Chemotherapy pathway - Illustrative example of good practice

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