Intelligence

National Cancer Action Team
Part of the National Cancer Programme

NHS

National Cancer Peer Review Programme

Manual for Cancer Services:

Chemotherapy Measures

Version 1.0

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Introduction

1.1 Aim of the Manual for Cancer Services

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 among 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.

The National Cancer Peer Review Programme, which is led by the National Cancer Action Team and includes expert clinical and patient/carer representation, provides important information about the quality of clinical teams and a national benchmark of cancer services across the country.

National quality measures for cancer services were first published in 2001 and were updated in 2004, 2008. The range of measures has subsequently been extended to cover virtually all cancer-sites and cross cutting cancer services (e.g. chemotherapy, radiotherapy). It is intended that the National Cancer Intelligence Network (NCIN) clinical reference groups will review the measures within the manual for cancer services annually to ensure they are clinically relevant and it is intended that the measures will underpin the NICE Quality Standards relating to cancer.

An independent evaluation of the National Cancer Peer Review Programme demonstrated strong support for the programme to continue, subject to reducing the burden of peer review and putting greater emphasis on outputs and outcomes as and when data becomes available.

In response to this the number of measures has been reduced by over one third in 2008 and more recently by a further 10%. In addition "Clinical Lines of Enquiry" (CLE) have been introduced, based on outputs/outcomes to support the Manual for Cancer Services. The revised process for peer review will be implemented in April 2011 but the measures contained within this manual will remain an integral part of the review process.

Compliance with the manual has not been centrally imposed. Although the NHS is not mandated to adhere to the measures in the Manual for Cancer Services, it is currently used by the National Cancer Peer Review Programme as part of their local assessment of cancer services and to provide a ready specification for commissioning of cancer services within a given locality.

1.2 Background and Context

Substantial progress has been made in cancer in the last decade, particularly since the publication of the NHS Cancer Plan in 2000. However, major challenges remain and in January 2011 Improving Outcomes: A Strategy for Cancer was published.

The strategy sets out how the future direction for cancer will be aligned with Equity and Excellence: Liberating the NHS in addition to meeting its stated aim to saving an additional 5,000 lives every year by 2014/15, aiming to narrow the inequalities gap at the same time.

The strategy acknowledges the importance of comprehensive information about cancer services for individual members of the public, cancer patients and their carers, healthcare professionals and commissioners.

1.3 Measures within the National Cancer Peer Review Manual

The peer review is changing its emphasis to focus on both clinical and patient outcomes. In order to achieve this, 'Clinical Lines of Enquiry' have been introduced and it is intended these outcome indicators will form part of the measures along with a reduced number of structure and process measures.

The development of cancer measures is an ongoing process in order to:

- reflect new NICE Quality Standards and clinical guidelines and revisions to existing NICE guidance;
- allow greater influence by users of cancer services and their carers;
- allow greater influence by clinicians;
- take account of possible modifications to measures following peer review visits;
- ensure the scope of measures encompasses the broader implementation of the Improving Outcomes: A Strategy for Cancer;
- reflect new initiatives such as lapco, information prescriptions.

The relationship between the NICE Improving Outcomes Guidance and Quality Standards and the Manual for Cancer Services is explained in more detail in appendix A.

1.4 Reviewing the Measures

The National Cancer Peer Review (NCPR) Programme aims to improve care for people with cancer and their families by:

- ensuring services are as safe as possible;
- improving the quality and effectiveness of care;
- improving the patient and carer experience;
- undertaking independent, fair reviews of services;
- providing development and learning for all involved;
- encouraging the dissemination of good practice.

The benefits of peer review have been found to include the following:

- provision of disease specific information across the country together with information about individual teams which has been externally validated;
- provision of a catalyst for change and service improvement;
- identification and resolution of immediate risks to patients and/or staff;
- engagement of a substantial number of front line clinicians in reviews;
- rapid sharing of learning between clinicians, as well as a better understanding of the key recommendations in the NICE guidance.

The NCPR programme has been keen to take the opportunity to reduce the burden on the NHS in line with the efficiency gains asked of all NHS organisations. The revised methodology will reduce the burden on the service without substantially impacting on the quality assurance process.

Appendix A

Interpretation of the National Manual for Cancer Services

1.1 Guidance Compared to Cancer Measures

The NICE Improving Outcomes Guidance is exactly what it says - guidance in general and indeed is excellent for this purpose. Guidance involves giving advice and recommendations on how things should be done now, in the future and sometimes on how things should have been done for sometime already. It may involve describing in effect the "perfect" service, using phrases like "the best possible", "to all patients at all times", etc. It may involve all-inclusive and far-ranging objectives and aspirations involving many agencies in long, interlinked chains of events and tasks which all have to be fulfilled before the desired outcome of the guidance is achieved. A particular person's accountability for each task is often not stated.

It may use influential and important ideas and models, which are however complex or not precisely definable, such as "network-wide patient care pathways" or "culturally-sensitive information". It always contains useful and necessary value judgements which use words like "sufficient", "appropriate", "robust" and "comprehensive", but it often has to leave unanswered the key question - what exactly is it which makes the issue under examination "sufficient", "appropriate", "robust" and "comprehensive" or not? It uses concepts which, although crucial, may not be measurable. It ranges widely from things which everybody gets right as a matter of course already through to principles which, if taken literally, nobody would comply with ever.

All these features, although they may sound unhelpful as described above, are present in all guidance documents and are part of the necessary and accepted style of guidance writing. Without this underlying type of mindset, guidance would not inspire, lead, motivate or guide and would probably be almost unreadable. The Manual for Cancer Services has to take a different approach. It is written for and only for the specific purpose of being used to assess a service against it, to aid self assessment and team development (a) by a peer review visit; (b) on a specific occasion; (c) a visit which has to be fair compared to visits to other services elsewhere and (d) to past and future visits to the same service. Therefore, the measures have to:

- be objective - with as little room as possible for arguments between assessors and assessed; and between different teams of assessors;
- be measurable - and at least capable of definitely being complied with or not;
- be specific - not addressing several issues at once or long, linked chains of tasks all being done by different agencies;
- be verifiable - by evidence produced for the visit; state who exactly is responsible for what - or nobody may take responsibility for anything;
- sometimes deal with the implications of the guidance - which may not have been explicitly stated but which are essential for anything to actually happen;
- be discriminating - it's no use spending time and money on assessing something which everybody gets right already;
- be achievable - it's no use committing everybody to permanent and automatic failure because of the way something is worded;
- be clear and unambiguous - the words will be taken to mean exactly what they appear to say, and therefore they have to say exactly what we mean and nothing else;
- pick out and address the most important issues - the peer review process is limited in its scope;
- be developmental - encourage continuous quality improvement and not produce destructive competition or a sense of failure;
- be sensibly and fairly related to previous measures - in order to be developmental - not just arbitrarily moving the goal posts.

All this results in the rather esoteric style of the manual. Please judge the measures on their merits in the light of the above and not in comparison to the guidance.

1.2 "The Responsibility for Assessment Purposes"

This refers to the fact that someone, or some group, is always held nominally responsible for compliance with each one of the quality measures. This has to be specified or, in terms of organising the peer review and collecting the results, it would be unclear who was being held as compliant or non-compliant or who the results could be attributed to. Where it is unclear who has responsibility there tends to be inertia. This attribution of responsibility does not necessarily commit a given person to actually carrying out a given task - this can be delegated according to local discretion, unless it is clear that a given task really is limited to ascertain group.

1.3 "Agreement"

Where agreement to guidelines, policies etc. is required, this should be stated clearly on the cover sheet of the three key documents including date and version. Similarly, evidence of guidelines, policies etc requires written evidence unless otherwise specified. The agreement by a person representing a group or team (chair or lead etc) implies that their agreement is not personal but that they are representing the consensus opinion of that group.

1.4 Confirmation of Compliance

Compliance against certain measures will be the subject of spot checks or further enquiries by peer reviewers when a peer review visit is under taken. When self assessing against these measures a statement of confirmation of compliance contained within the relevant key evidence document will be sufficient.

1.5 "Quality" Aspects of Cancer Service Delivery

Many of the measures expect that policies, procedures, job descriptions and other documents will be in place. In reviewing compliance with the measures (for instance measure met or not) during validation, verification and visits, reviewers will look only for the presence of such documents, unless aspects of the content are specified in the wording of the measure. Where some aspect of the content is specified then this will be taken into account in determining compliance. As part of the improvement of cancer services, reviewers may comment on the content of documents and agreements but this will not affect the determination of compliance.

Work is ongoing to enable us to subject more of the "quality" aspects of cancer service delivery to objective measures for future rounds of peer review.

Many reviewers have a legitimate and valuable contribution to make by way of comments on areas which are a matter of opinion rather than fact or authoritative and evidence based measures. This recognises the qualitative as well as quantitative approach to reviews. This contribution can be made by way of a textual report in addition to the objective recording of compliance against the measures. This report is separate from the review against the measures and is inevitably more subjective and open to debate. However, there are many ways in which it can add to the overall picture gained from the peer review.

1.6 Structure of the Measures

Each measure has a three part number, for example 11-1A- 201j.

- The first part indicates the year the measure was first issued, for example 11 is 2011.
- The second part relates to a particular topic see below, for example 1A.
- The third part is made up of a unique measure number in the topic and where relevant a suffix letter indicating a specific tumour and cross cutting services, for example 201j (see below).

Index of Suffix Letters

a - Generic to all tumour sites	**r** - Specialist Palliative Care specific
b - Breast specific	**s** - Chemotherapy specific
c - Lung specific	**t** - Radiotherapy specific
d - Colorectal specific	**u** - User Group specific
e - Gynaecology specific	**v** - Rehabilitation specific
f - UGI specific	**w** - Complementary Therapy specific
g - Urology specific	**x** - Psychological Support specific
h - Haematology specific	**y** - Acute Oncology
i - Head and Neck specific	
j - Skin specific	

Each network will be made up of several localities/trusts and several NSSGs / cross cutting groups, each with multiple MDTs and services. These MDTs and services will each need to demonstrate compliance with the relevant quality measures. A network overview will be developed by bringing together the findings relating to individual MDTs and services as well as those concerning network organisation and structures.

Manual for Cancer Services On-line

An on-line version of the Manual for Cancer Services has been developed. The on-line version allows individuals to identify and extract measures by tumour site, organisation type and subject area in a variety of formats.

The on-line manual can be accessed from the CQuINS web site at http://www.cquins.nhs.uk.

CHEMOTHERAPY MEASURES

INTRODUCTION

The revised chemotherapy measures are based on the measures from the Manual for Cancer Services 2004, but take into account:

- The revisions recommended by the peer review measures revision group, following the 2004-2007 round of the cancer peer review.
- The recommendations of the report of the National Chemotherapy Advisory Group (NCAG), 2009.
- Revisions to Intrathecal Chemotherapy (ITC) measures following the updated national guidance, (HSC 2008/001 Updated national guidance on the safe administration of intrathecal chemotherapy).

Since the publication of the measures of 2004, new guidance and corresponding peer review measures have been produced for children's cancer services and teenage and young adults' (TYAs') cancer services. Children's chemotherapy services are delivered almost exclusively in facilities designated specifically for the use of children. Thus, there is a separate set of measures for children's chemotherapy, included in topic 7, not here and reviewed separately as part of the overall review of children's cancer services. The measures in this topic (3S) apply to the treatment of all patients outside the children's age group, including TYAs.
The NCAG report recommended a systematic, integrated, network-wide approach to the management of urgent problems associated with malignant disease and its treatment. This has been termed 'acute oncology'. This is not limited to chemotherapy, but it includes a number of aspects of chemotherapy practice and thus, certain aspects of chemotherapy are now reviewed as part of the acute oncology measures (topic 3Y). These include the underlying network configuration of chemotherapy and supporting pharmacy services, since there is a requirement for it to be included as part of the network review of the whole configuration of acute oncology.

NOMENCLATURE

Within the network measures a number of groups have been defined. These groups each need a name for the purpose of the measures, and for data collection from the peer review. The names are purely labels for the measures. Provided a group is formed and put forward for assessment against the appropriate set of measures, the name used locally is a local matter. The result of its review will be recorded and collated for the peer review database under its measures' name, to avoid confusion.

For the purposes of the chemotherapy measures and this part of the cancer services peer review, the following terms are used, together with the following meanings:

'**Oncology**' here refers to the collection of practices by the collection of subspecialties, which deals with the non-surgical treatment (here, by means of drugs) of **malignant** disease by non-surgeons. These measures are not written to apply to chemotherapy in the treatment of **non-malignant disease**. The same or similar quality measures may or may not be used locally for non-malignant disease. This is entirely at local discretion and is outside the scope of the cancer peer review measures.

Some malignancies are most commonly treated non-surgically by haematologists. This area of practice is here termed '**haemato-oncology**'. Some malignant diseases are most commonly treated non-surgically by oncologists who are not haematologists and not surgeons. This area of practice is termed '**solid tumour oncology**'. Some malignant diseases fall variably into either or both areas of practice, depending on local working practice. The relative boundaries of both areas of practice are a matter entirely for local discretion and definition and are not a matter for the measures or peer review.

Oncologist is used as a collective term which may apply to haematologists, clinical oncologists and medical oncologists involved in the non-surgical treatment, in this case by chemotherapy, of malignant disease. Which group or groups of specialists the term applies to in a given instance, should be evident from the context.

The term '**chemotherapy**' refers to the use of those cytotoxic agents commonly understood and accepted as being covered by this term. The inclusion of certain other agents which may or may not be understood to fall clearly into this group is permissible -such as, biological therapy and small molecule tyrosine kinase inhibitors. The exact extent of the drugs to be included under the remit of the measures is a matter for local discretion unless otherwise stated in the measures themselves. It will largely be manifested by which regimens and

which supportive drugs are named in the network and local lists of treatment algorithms and protocols.

For this set of measures and this round of peer review '**systemic chemotherapy**' is being reviewed, a term which, for peer review purposes covers intravenous, oral, subcutaneous and intramuscular chemotherapy. Topical and intracavitary chemotherapy is not included. **Intrathecal** chemotherapy is dealt with in a separate section, topic 11-3S-3.

For the purposes of peer review, a chemotherapy **regimen** is defined by the therapeutic chemotherapy drugs used, often expressed as an acronym e.g. 'FEC'. A change of one or more of these drugs themselves would normally be necessary for it to be classed as a change of regimen. In some cases major changes in the dose or route of administration of one or more of the drugs effectively changes the regimen but these cases are generally known and recognised nationally. A given network is free to choose any further changes which they classify as changing the regimen, as long as it is in accord with the above definition and national exceptions; i.e. they are free to make the definition of a regimen narrower, but not wider.
For the purposes of peer review, a **treatment protocol** is defined as constituting all the parameters specified in the bullet points in chemotherapy measure 11-3S-122. A change in any of these parameters would change the treatment protocol but any change other than the therapeutic drugs themselves (apart from the national and local exceptions specified above) would change only the protocol, not the regimen as well.

For the purposes of peer review a chemotherapy **treatment algorithm** may be described as a guideline which specifies the acceptable ranges of regimen options for named steps on the patient pathway. Treatment algorithms are cancer site-specific. They are not specific to individual patients, i.e. they are not individual treatment plans. Thus, a treatment algorithm for breast cancer would include a statement of the range of regimens agreed as acceptable for adjuvant chemotherapy and for first, second and third line palliative chemotherapy etc. Illustrative examples of treatment algorithms in different formats may be found in the appendix 1. There may be other formats which would be acceptable to the reviewers.

Thus, a change of regimen or order of regimens may no longer comply with a previous treatment algorithm, but a change of one of the minor aspects of a treatment protocol would still comply.

In the measures, chemotherapy is referred to as being given over a complete period of treatment known as a course, which consists of giving the drugs over a repeated pattern known as a **cycle**. For entirely oral chemotherapy, a cycle may be defined by the length of time in between mandatory assessments. The maximum intended number of cycles, and therefore the intended length of the course, may be **pre-determined or fixed**, or dependent on various factors and therefore **indeterminate or variable** from the outset. The separate occasions when drugs are given within a cycle are termed **administrations**. These are usually understood to refer to occasions of parenteral administration rather than, say, daily oral doses, oral treatment being referred to in the conventional way of pharmacological prescriptions.

The nomenclature used here, (courses, cycles and administrations) has the benefit of more or less common usage and understanding. It may change after the publication of the proposed, National Systemic Anti-Cancer Therapy Dataset.

ORGANISATION OF THE SERVICE (Excluding Intrathecal Chemotherapy)

Adult chemotherapy services are organised in a variety of ways, within and between hospitals. They cover two main branches of this activity; solid tumour oncology and haemato-oncology, with some conditions being divided variably between the two branches, depending on local clinical referral patterns. The chemotherapy service(s) also relate in various ways to the local, supporting oncological pharmacy services. In order to allow for peer review of all types of local service configuration and to make things clear for review purposes, the measures approach the chemotherapy service as follows:
The service is reviewed for three separate components although their activities are inter-related and inter-dependent in practice.

i) The Network Aspects of Chemotherapy

- This has measures for the Network Board in topic 1A to establish a network chemotherapy group and identify the network heads of service for clinical chemotherapy and oncological pharmacy (see below).
- There are also measures for the Network Chemotherapy Group in topic 1E-1s, to co-ordinate chemotherapy across the network.
- These network aspects will be reviewed as one entity for the whole network. For example there should be one single network chemotherapy group. The compliance with the network chemotherapy measures will

count towards the network board or the network chemotherapy group, as appropriate.

ii) The Clinical Chemotherapy Service

- This has measures in topic 3S-1. Its extent - the hospitals or parts of a hospital, and the subspecialties (solid tumour oncology or chemotherapy for haemato-oncology) which it covers, will have been specified and declared by the network board. There may be several services across the network.
- It should have only one named head of service who, for review purposes is responsible for the measures in topic 3S-1, for the whole of that particular clinical chemotherapy service.
- The whole of that particular clinical chemotherapy service across the hospitals and subspecialties which it covers will be considered as one entity when the service is reviewed against the measures. For example, for a measure referring to facilities such as wards, all the relevant wards across the service as specified would need to comply for the service itself to comply.

iii) The Oncology Pharmacy Service

- This has measures in topic 3S-2. Its extent - the subspecialties it supports (solid tumour oncology or chemotherapy for haemato-oncology malignancy) and in which named hospitals they take place, should be declared. There may be several services across the network.
- It should have only one named lead pharmacist who, for review purposes, is responsible for the measures in topic 3S-2 for the whole of that particular oncology pharmacy service.
- All the work of that particular service in supporting all the activities will be considered as one entity when the service is reviewed against the measures. For example the provision of designated pharmacists would need to cover all the relevant activities declared, for the service to comply.

REVIEWING CHEMOTHERAPY - (Excluding Intrathecal Chemotherapy)

- Establishing the chemotherapy and oncology pharmacy services within the network will be reviewed as part of the Acute Oncology measures in topic 3Y.
- The Network Chemotherapy Group is the responsibility of the Network Board, reviewed in topic 1A.
- Functions of the Network Chemotherapy Group, reviewed in topic 1E-1s.
- Functions of the clinical chemotherapy service reviewed in topic 3S-1, and of the oncology pharmacy service reviewed in topic 3S-2.

DELINEATING AND REVIEWING THE INTRATHECAL CHEMOTHERAPY SERVICE

Measures for the review of Intrathecal Chemotherapy (ITC) have been written, based on the National Guidance on Intrathecal Chemotherapy (HSC2008/001) these are the responsibility of the CE of each trust which delivers ITC. The measures are contained in a separate section, section 3S-3 of the Manual for Cancer Services and instructions on delineating the trust's ITC service and its review are found therein. Notes on how those measures relate to the general chemotherapy measures in sections 3S-1 and 3S-2 will follow.

Glossary

CCS	**Clinical chemotherapy service**
C-PORT	**Chemotherapy Capacity Planning Tool**
CTCAE	**Common terminology for adverse events.**
FT1/2	**Foundation trainee, level one/two.**
HSC	**Health service circular.**
IT	**Intrathecal.**
ITC	**Intrathecal chemotherapy.**
NAOG	**Network acute oncology group.**
NCG	**Network chemotherapy group**
NCAG	**National Chemotherapy Advisory Group.**
NCNG	**Network chemotherapy nurses group.**
NICE	**National Institute of Clinical Excellence.**
NOPG	**Network oncology pharmacy group.**
NPSA	**National Patient Safety Agency.**
RRR	**Rapid response report.**
SLA	**Service level agreement.**
WHO	**World Health Organisation.**

TOPIC 11-1A-3s - NETWORK BOARD MEASURES FOR CHEMOTHERAPY

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE

The responsibility for review purposes for the measures in this section lies with the Chair of the Network Board.

Chemotherapy Heads of Service

11-1A-301

The Network Board should agree, in consultation with lead clinicians of the acute trusts involved, a single named head of service for each clinical chemotherapy service in the network.

They should have regular involvement in the use of chemotherapy for malignant disease as part of their list of responsibilities or work plan besides their specific duties as head of service.

Note:

The head of service may be a medical, nursing or pharmacist practitioner, and may or may not also be a lead nurse or lead pharmacist.

Compliance: The named head of service for each service agreed by the Chair of the Network Board and the lead clinicians of the acute trusts involved.

The reviewers should enquire of the heads of service timetables/ job plans, as evidence that they are involved in the treatment of patients with chemotherapy.

Note: The timetables are not being reviewed regarding the adequacy of the clinician's time for certain tasks.

Lead Pharmacists for Oncology Pharmacy Services

11-1A-302

The Network Board should agree, in consultation with lead clinicians of the acute trusts involved, a single named lead pharmacist for each oncology pharmacy service, who should be one of the designated oncology pharmacists.

Compliance: The named lead pharmacist for each service agreed by the Chair of the Network Board and the lead clinicians of the acute trusts involved.

The Network Chemotherapy Group

11-1A-303

There should be a single network chemotherapy group (NCG) which includes the following representatives:

- a representative from each multi-professional team in the network (see measure 11-3S-107);
- a representative from the network oncology pharmacy group if such a group has been formed (see measure 11-1E-107s);
  Note: This would normally be the chair of the oncology pharmacy group.
- a representative from the network chemotherapy nurses group if such a group has been formed (see measure 11-1E-109s).
- named secretarial/administrative support.
  Note: The Chair of the NCG should be a member of the Network Acute Oncology Group (NAOG)(See measure 11-1A-304y)

There should be terms of reference agreed for the NCG which include:

The group should be recognised as;

- the Network Board's primary source of advice on issues relating to chemotherapy in the network;
- the group with corporate responsibility delegated by the Network Board for ensuring co-ordination and consistency across the network for implementing the chemotherapy measures, implementing the NICE guidance on applicable chemotherapy agents, and for the work of the multi-professional teams;
- the group with corporate responsibility delegated by the Network Board for establishing the oncology pharmacists group and the chemotherapy nurses group and overseeing their work if they are established;
- consulting with the Network Site Specific Groups (NSSGs) on the chemotherapy aspects of clinical and referral guidelines.

Notes: There may be additional points in the terms of reference and the group may have other duties.

The group may be part of another network group e.g. the NAOG provided the membership and terms of reference are fulfilled.

Compliance: The named members and what they represent, together with the named chair agreed by the Chair of the Network Board.

The named members with responsibility for users' issues and information for patients.

The terms of reference, agreed by the Chair of the Network Board and the Chair of the Network Chemotherapy Group (NCG).

Note: An agreed extract or summary is sufficient if it shows compliance with the measure.

Network Lead Pharmacist

11-1A-304 A single pharmacist representative from the NCG should be designated as the network lead pharmacist.

Note: This would normally be the Chair of the Oncology Pharmacy group.

They should have a list of responsibilities for the role of the network lead pharmacist.

The time available for these responsibilities should be specified.

Compliance: The named pharmacist, list of responsibilities and specified time agreed by the Chair of the NCG or Chair of the Network Board if the Chair of the NCG is also the network lead pharmacist.

Network Lead Chemotherapy Nurse

11-1A-305 A single chemotherapy nurse representative from the NCG should be designated as the network lead chemotherapy nurse.

Note: This would normally be the Chair of the Chemotherapy Nurse Group.

They should have a list of responsibilities for the role of the network lead chemotherapy nurse.

The time available for those responsibilities should be specified.

Compliance: The named nurse, the list of responsibilities and the specified time for, agreed by the Chair of the NCG or Chair of the Network Board if the Chair of the NCG is also the network lead chemotherapy nurse.

TOPIC 11-1E-1s - FUNCTIONS OF THE NETWORK CHEMOTHERAPY GROUP

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE

The responsibility for review purposes for the measures in this section lies with the Chair of the Network Chemotherapy Group.

It is essential that the introduction to the chemotherapy measures is read before applying them, especially the section on nomenclature, which has been significantly revised.

Network Chemotherapy Group Meetings

11-1E-101s The NCG should meet regularly and record attendance.

Compliance: Documentation to show that a meeting took place within six months prior to the peer review visit/self assessment.

A programme of meeting dates.

An example of an attendance list.

The Network Chemotherapy Group Annual Review, Work Programme and Report

11-1E-102s The Chair of the NCG should have an annual review with the network lead clinician.

The NCG should have agreed a work programme with the board for the contracting year in which the peer review visit/self assessment takes place.

The NCG should have produced an annual report for the board for the complete calendar or contacting year prior to the peer review visit/self assessment

Compliance: Documentation sufficient to show that a review meeting took place with the network lead clinician in the year prior to the peer review visit/self assessment.

The work programme agreed by the Chair of the NCG and the Chair of the Network Board.

The annual report, agreed by the Chair of the NCG.

Note: An agreed extract or summary of a document is sufficient if it shows compliance with the measure.

TREATMENT ALGORITHMS

Introduction.

Each NSSG in consultation with the NCG should agree a set of site specific chemotherapy treatment algorithms for the network (see the definitions of treatment algorithms, regimens and protocols under 'nomenclature' in the introduction to the chemotherapy measures). This requirement is covered in the site-specific measures for each NSSG. There are measures relating to these treatment algorithms in this section, below, for the NCG and measures for the CCS in section 3S-1 relating to the algorithms and also to chemotherapy treatment protocols.

Policy for Preventing Regular Deviation from the NSSG Agreed Treatment Algorithms

11-1E-103s The NCG should agree a written policy with the multi-professional teams for preventing regular deviation from the treatment algorithms agreed with the NSSGs.

The policy should state:

- the exceptional circumstances under which such a deviation could occur;
- the procedure which is then required to authorise it.

Note: The NCG should produce this policy for its compliance with this measure and the multi-professional team should agree to abide by it for its compliance with its relevant measure.

Compliance: The written policy, agreed by the Chair of the NCG.

Network Review of Algorithm Deviations

11-1E-104s The NCG should, at one of its meetings, review the records from the

Network's clinical chemotherapy services (CCSs), of the deviations from the NSSG agreed treatment algorithms.

Note:

It may not be possible to review all the CCSs at one meeting.

Compliance: Documentation to show that a review meeting took place in the year prior to the self assessment/peer review visit.

ERROR RECORDING AND REPORTING

Network Chemotherapy Error Review

11-1E-105s The NCG should review the reported errors and the resulting actions of the CCSs, at least annually.

Compliance: An extract of the minutes of a relevant meeting of the NCG during the year prior to the assessment.

Note: If no such errors have occurred for reporting, in any of the CCSs associated with the NCG, since the publication of these measures or peer review assessment, as relevant, this measure is considered to have been complied with.

CRITERIA FOR ACTING AS AN ASSESSOR OF COMPETENCE

Introduction

From the time of publication of these measures, the following may be considered initially capable and authorised to assess staff competency and, therefore, automatically competent, themselves:

Note: Networks may wish to restrict initial competency and/or the initial capability of acting as an assessor more strictly than according to what is outlined next. However, they should, in that case, take into account the immediate effect that would have on the treatment capacity of CCSs.

- consultant oncologists, in the protocols relating to the tumour types they sub specialise in - for prescribing chemotherapy;
- chemotherapy nurses at band 7 or above or lead chemotherapy nurses - for administering chemotherapy;
- designated oncology pharmacists - for prescription checking and dispensing chemotherapy.

The following measure then relates to those who, in addition to the initial assessors, may subsequently be authorised as assessors for the ongoing practice of the chemotherapy services.

Criteria for Acting as an Assessor of Competence

11-1E-106s The NCG should agree the ongoing criteria necessary for a staff member (other than those considered initially capable as assessors) to be considered capable of assessing the competency of other staff to practice in the chemotherapy services of the network.

The criteria should specify:

- the professional staff group or groups the assessor should be a member of;
- the particular competencies for which they are deemed capable as an assessor;
- that they should themselves be currently authorised as competent for those competencies;
- any additional criteria (for illustration only, for instance; number of procedures) which the network agrees are necessary;
- the network should agree the criteria which determine when a.) competency and b.) the authorisation of capability as an assessor should be reviewed.
  Notes: For illustration only, this may include a fixed length of time, then a mandatory review; review when the case throughput is considered low; or other criteria. It may be dependent on the particular range of competencies being considered. As and when national guidance from professional bodies becomes available this should be used. Until then, these criteria are for the network to agree.
  Assessors would usually deal with members of their own profession, but there may be exceptions to this.

Compliance: The criteria, agreed by the Chair of the NCG.

THE NETWORK ONCOLOGY PHARMACY GROUP

Membership and Terms of Reference of Network Oncology Pharmacy Group

11-1E-107s There should be a single oncology pharmacy group for the network with a named chair.

The members should include as a minimum;

- a representative from each of the oncology pharmacy services put forward for review in the network. The representative should be a designated pharmacist or lead pharmacist (see measures 11-3S-201 and 11-3S-202).

The network oncology pharmacy group (NOPG) should agree terms of reference with the NCG. They should include the following:

- the group should be the primary source of pharmaceutical advice on chemotherapy issues and should promote co-ordination and consistency relating to these across the network.

Note:

The group may choose to agree additional terms of reference with the NCG.

Compliance: The named members and named chair, agreed by the Chair of the NCG.
The terms of reference agreed by the Chair of the NCG and the Chair of the NOPG.

Network Oncology Pharmacy Group Meetings

11-1E-108s The NOPG should meet regularly and record attendance.

Compliance: Documentation to show that a meeting took place within six months prior to the peer review visit / self assessment.
A programme of meeting dates.
An example of an attendance list.

NETWORK CHEMOTHERAPY NURSES GROUP

Membership and Terms of Reference of Network Chemotherapy Nurses Group

11-1E-109s There should be a single group for the network representing nurses who administer chemotherapy, with a named chair drawn from the membership. The members should include as a minimum;

- a nurse representative who administers chemotherapy from each of the clinical chemotherapy services put forward for review in the network.

The group should agree terms of reference with the NCG. They should include the following;

- the group should be the NCG's primary source of nursing advice on chemotherapy issues and should promote co-ordination and consistency relating to these across the network.

Note:

The group may choose to agree additional terms of reference with the NCG.

Compliance: The named members and named chair agreed by the Chair of the NCG.
The terms of reference agreed by the Chair of the NCG and the Chair of the Network Chemotherapy Nurses Group (NCNG)

Network Chemotherapy Nurses Group Meetings

11-1E-110s The NCNG should meet regularly and record attendance.

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE	
Compliance:	Documentation to show that a meeting took place within six months prior to the peer review visit / self assessment. A programme of meeting dates. An example of an attendance list.
24 Hour Telephone Advice Service For Patients	
11-1E-111s	The NCG, in consultation with the CCSs heads of service, should agree the minimum specification of the 24-hour service which should stipulate that: • It is available 24-hours a day, seven days a week, for telephone advice to patients having chemotherapy, on the side effects and complications and how to obtain help and treatment for them; • It covers the whole network; • It may be divided into more than one local service each covering one or more localities, or one or more CCSs, each local service with its own set of contact numbers. This set of local arrangements i.e. the configuration of the network-wide service should be agreed as part of the minimum specification; • Each local service should be staffed at any one time by at least one member of staff making up a 24-hour duty rota; • The level of training or professional qualifications necessary for these staff, should be agreed by the network chemotherapy group as part of the minimum specification.
Compliance:	The minimum service specification agreed by the Chair of the NCG, covering the points specified above. *Notes*: *The network, for its compliance with this measure, should produce the arrangements and the individual clinical chemotherapy services for their compliance with their relevant measure should agree to abide by them and provide their contribution to the staffing.* *A CCS may agree to provide a 24-hour rota exclusively for their own service, or may contribute staff to a service shared with other CCSs. This is for agreement with the NCG*

TOPIC 11-3S-1 - CLINICAL CHEMOTHERAPY SERVICES

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE

The responsibility for review purposes for topic 11-3S-100 lies with the head of service. The measures in this section should be applied to each individual CCS and the compliance counts as the review of that service.

It is essential that the introduction to the chemotherapy measures is read before applying them, especially the section on nomenclature, which has been significantly revised.

Head of Service Responsibilities

11-3S-101 The head of service should agree a list of responsibilities for the role with the lead cancer clinician(s) of the trust(s) involved in the CCS, and the head of service's line manager.

Note:

The head of service could be medically qualified (consultant solid tumour oncologist or haemato-oncologist), nurse or pharmacist.

Compliance: The list of responsibilities agreed by the lead cancer clinician(s) and the line manager.

Lead Chemotherapy Nurse

11-3S-102 There should be a single lead chemotherapy nurse for the CCS.

They should have regular personal involvement in chemotherapy administration as part of their timetable, besides their duties as lead chemotherapy nurse.

The head of service and the lead chemotherapy nurse's line manager should agree a list of responsibilities for the role of the lead chemotherapy nurse.

Compliance: The named nurse agreed by the head of service and the nurse's line manager.

The timetable or work plan.

The list of responsibilities, agreed by the head of service, the line manager and the nurse.

Note:

The timetable or work plan is to provide evidence that they are involved in chemotherapy administration, not to assess the amount of time available for the role of lead chemotherapy nurse.

CHEMOTHERAPY FACILITIES - Measures 11-3S-103 to 11-3S-106

Named Wards

11-3S-103 There should be a written policy whereby patients having planned admissions for IV chemotherapy for malignant disease are admitted preferentially to named wards where it is agreed as part of the ward's regular activity.

Note:

Day case chemotherapy may also be given on such wards.

Wards with stricter policies than above, e.g. those reserved exclusively for chemotherapy, are also considered compliant with this measure.

Compliance: The policy, naming the wards, agreed between the head of service and the relevant hospital manager.

The reviewers should enquire of the hospital practice.

Specified Room Policy

11-3S-104 When outpatient or day case chemotherapy is being given in wards/areas other than those specified in the above measures, it should only be given in specified room(s) covered by a policy whereby:

- on the days that chemotherapy is being given the room(s) should only be used for

this purpose or other outpatient/day case aseptic treatment or procedures.

Notes:

Such terms as departments, units, suites and facilities, etc are all difficult to define with precision but they are all made up of a room or rooms.

Compliance: The policy specifying the room(s) agreed between the head of service and the relevant hospital manager.

The reviewers should enquire of the hospital's practice.

Provision of Protocols and Equipment

11-3S-105 The areas/wards/rooms identified in measures 11-3S-103 and 11-3S-104 should have available in them:

- The regimen details as per the CCS list of treatment protocols for the regimens in use.
- Protocol documents and equipment for the management of at least the following emergencies:
  i. anaphylactic shock;
  ii. extravasation of cytotoxics;
  iii. cardiac arrest;
  iv. spillage of cytotoxics.

Compliance: The areas/wards/rooms should be reviewed.

Temporary Storage and Preparation Area

11-3S-106 The areas/wards/rooms identified in measures 11-3S-103 and 11-3S-104 should have within them, or adjacent to them, a separate and identified area for the temporary storage of chemotherapy agents which have been dispensed from pharmacy, and for tasks involved in preparation and delivery of treatment.

Note:

These tasks refer to those which the service decides do not need to be done in a specialised, aseptic pharmacy preparation unit.

Compliance: The areas/wards/rooms should be reviewed.

THE CHEMOTHERAPY MULTIPROFESSIONAL TEAM

Introduction

The chemotherapy multiprofessional team has taken the place, from the point of view of peer review, of the former 'local chemotherapy group.'

The Chemotherapy Multi-professional Team

11-3S-107 There should be a single multi-professional team for the service, with the following minimum membership:

- consultant oncologist;
- consultant haemato-oncologist;
  Note:
  Where there is only one oncologist on the team, they should be the head of service. A consultant haemato-oncologist is essential if there is a chemotherapy practice in haematological malignancy covered by the service.
- designated oncology pharmacist;
  Note:
  Where there is only one pharmacist on the team, this should be the lead pharmacist.
- nurse administering chemotherapy;
  Note:
  Where there is only one nurse on the team, this should be the lead nurse.

- relevant hospital manager.

Note: The service may agree additional members besides those specified above.

The title given to this team in the measure is chosen to distinguish it from the site-specific 'MDTs'. The actual name by which this group of people may be referred to locally is not subject to review. What matters is that a group is put forward for review against the relevant measures.

The team should have agreed terms of reference with the head of service which specify that it has delegated responsibility from the head of service to be the team responsible for coordinating the multi-professional opinion across the service and being the final common path for advising the head of service on the following:

- implementation of the chemotherapy measures;
- monitoring of, off protocol treatments;
- clinical governance, audit, quality assurance and quality control and documentation and investigation of incidents;
- risk management;
- change management, including introduction of new protocols, techniques and technologies;
- maintenance of training and competency and matching staff functions to competency.

The terms of reference should specify that on quality management the team should report to a clinical governance committee in the host trust, outside the clinical chemotherapy service.

Note:
How the service uses the team for these functions is at the service's discretion provided this measure and the next two measures are fulfilled.
It is recommended that there is one team for one service. It is acceptable however, in a network for a team to cover more than one service but this should be clearly indicated in the terms of reference. In this case, it would be expected that the named membership represented all services and the team would need to report to the clinical governance committees of each separate trust for the service hosted by that trust. There should, on no account be more than one team with the above terms of reference, for any one service.
If a team oversees more than one service, peer review would record results as relating separately to each of the team's services; documentation for compliance would need to relate as relevant to only that service and reviews would count as service reviews not team's reviews.

Compliance: The named members and what professional role they represent, agreed by the head of service.

The terms of reference agreed by the head of service.

Multi-professional Team Meetings

11-3S-108 The multi-professional team should meet regularly.

It should have met prior to the first review following publication of these revised measures.

Note:
The frequency of meetings is at the service's discretion.

Compliance: A program of dated meetings, agreed by the head of service.

An extract of the minutes of a meeting.

Representation on the Drugs and Therapeutic Committee

11-3S-109 At least one member from those listed specifically in measure 11-3S-107 should be a representative on the Drug and Therapeutics Committee(s) of those trust(s)

encompassed by the local team's services.

Note: If the multi-professional team is contained within the trust Drug and Therapeutics Committee, and it has the membership to fulfill measure 11-3S-107, and it encompasses services entirely within the trust, then this measure is automatically fulfilled.

Compliance: The membership list of the trust's Drug and Therapeutics Committee(s).

Representation on the Network Chemotherapy Group

11-3S-110 The multi-professional team should send a team member as a representative to at least two thirds of the NCG meetings.

Compliance: The attendance record of the NCG.

Error Recording and Reporting

11-3S-111 The CCS should record and report errors according to the host trust error recording system and agree actions with the relevant clinical governance body of the trust.

The CCS should report the errors and agreed actions to the NCG at least annually for review.

Compliance: The reviewers should enquire as to the working practice of the service regarding reporting errors to and agreeing actions with, the trust.

The report(s), at least annually, to the NCG.

Note: If no errors have occurred since the publication of these measures or most recent peer review assessment, as relevant, the practice is deemed to have been compliant.

FURTHER PRE-TREATMENT CONSULTATION

Introduction

The NCAG has set a requirement that patients who are about to undergo a course of chemotherapy should be able to have a separate further consultation with a health professional, prior to starting their course and after any consultations where the chemotherapy treatment plan is first agreed with them and they receive the associated patient information.

This further consultation is to try and ensure that they have had time to fully understand the implications of undertaking the course of treatment and to provide an opportunity for them to ask questions which they have had ample time to formulate.

Which particular health professionals carry out this further consultation and how the service carries out the complete processes of holistic assessment and obtaining informed consent in relation to this consultation is not the subject of this measure. Neither is it intended to ascertain if all patients attend for it. It is just to ensure that the service has provided for such consultations.

The NCAG requirement is for the consultation to take place 'ideally' on a separate day from previous ones but as this might often be impractical it should take place, if on the same day, then with 'sufficient' time having elapsed to enable it to fulfill the above aims. 'Sufficient' is impossible to measure objectively, however, and the reviewers should exercise judgment over this.

Further Pre-Treatment Consultation

11-3S-112 There should be a consultation incorporated into the patient pathway of the service which fulfils the following:

- it is for each patient, prior to starting a new course of chemotherapy, whether it is their first course or they have previously undergone a course or courses of chemotherapy;
- it takes place with a registered health professional;
- it is for the patient individually and, if needed, their carers; not as part of a group of patients;
- it takes place separately from and after any consultations at which the chemotherapy treatment plan is agreed with them;
- it has time specified for it.

Note: Compliance with having specified time may be demonstrated by any of the

following:

- *specified periods in time tables or job plans of named personnel, when they will be available for this task,*
- *specified slots in outpatient clinics or chemotherapy departments,*
- *evidenced by appointments or appointment times prior to the timed start of chemotherapy administrations.*

Compliance: The patient pathway.

Evidence of specified time as above.

The reviewers should enquire as to the working practice in relation to this consultation.

CHEMOTHERAPY CHECKING MEASURES

Introduction

The term 'check' is used in the measures to denote any instance where an observation is compared with a reference, whether a measurable quantity or a piece of factual information. Some types of check have acquired particular technical terms such as 'verification procedure'. Some of the individual measures may be found in the oncology pharmacy section.

The checks are required to be performed whenever practicable using methods which require an active response rather than a passive 'yes' or 'no', to avoid mistakes caused by the phenomenon of 'involuntary automaticity' e.g. in checking patient identity; asking 'are you Mrs Jones?' and receiving the passive response 'yes', is inadequate as it can lead to the wrong reply by, for instance, a nervous patient who has hearing difficulties. The correct procedure in this case would be to ask 'what is your name, please?' which requires the active response, 'Mrs Jones'.

Patient Identification Procedure

11-3S-113 There should be a protocol for checking the identification of patients, which specifies at least the following:

- the stages in the pathway at which this check is to be performed;
- the minimum qualifications and professional discipline of the personnel who should be involved;
- how the check achieves an active rather than a passive response;
- corrective strategies, i.e. who to inform and what action to take if the check reveals an error.

Compliance: The protocol, agreed by the head of service.

The reviewers should enquire as to the working practice of the department regarding this protocol and observe examples of practice.

CHECKS PRIOR TO THE PRESCRIPTION OF THE FIRST CYCLE

Introduction

Stimulated partly by the advent of electronic prescribing systems, some services have viewed the process of prescribing as being subdivided into several steps, given various names such as 'planning, authorising, and confirming' etc. This measure requires that all of the checks mentioned in it have been performed at some stage or other before the point of no return has passed and potentially costly drugs are being prepared for the patient.

Checks Prior to the Prescription of the First Cycle

11-3S-114 There should be a protocol for checks prior to prescribing the first cycle covering at least the following checks:

- history of specific diseases or conditions affecting fitness for chemotherapy. This includes that the minimum physical and investigational requirements have been met;
- performance status;
- prior history of chemotherapy;
- current patient medication affecting chemotherapy;
- that informed consent has been obtained;

- regimen against departmental protocols;
- that a holistic assessment has been carried out.

For each of these the protocol should specify at least the following:

- the minimum qualifications and professional discipline of the personnel who should be involved;
- how the working practice of the department prevents the check being omitted;
- how the check achieves an active rather than a passive response.

Compliance: The protocol, agreed by the head of service.

The reviewers should enquire as to the working practice of the department regarding this protocol and observe examples of practice.

Checks Prior to Administration

11-3S-115 There should be a protocol for checks prior to any administration covering at least the following checks:

Note: These will not normally take place on one occasion or all be done by one person. The list contains some checks which in some services may be known collectively as the 'verification procedure'.

- critical test results;
- regimen and individual drug identification;
- diluents and dilution volumes, and any hydration;
- that supportive drugs have been given as per prescription;
- administration route and duration;
- cycle number;
- the administration as per the schedule within the cycle;
- history of toxicities and complications from previous cycles;
- that the minimum monitoring requirements by physical examination and by investigation are being met;
- dose modifications or delays consequent on the above toxicities;
- response assessment according to the relevant regimen and treatment intention.

For each of these the protocol should specify at least the following:

- the qualifications and professional discipline of the personnel who should be involved;
- where in the patient's chemotherapy pathway the check happens;
- how the working practice of the department prevents the check being omitted;
- how the check achieves an active rather than a passive response;
- corrective strategies, (and for quantitative parameters, tolerances and action levels), i.e. who to inform and what action to take if the check reveals an error or need for action.

Compliance: The protocol, agreed by the head of service.

The reviewers should enquire as to the working practice of the department regarding this protocol and observe examples of practice.

TRAINING

Introduction

Nomenclature

For the purpose of these peer review measures, the term **'competence'** may be used to designate the ability to safely, efficiently and correctly (i.e. competently,) carry out a specified area of practice which a staff member needs to demonstrate. The term '**competency**' is taken to mean the state of having gained competence. They may then be referred to as possessing that specified competency and may have a list of various such competencies which they possess and which make up their **training record**. It is also commonly used in a subtly different way, to designate, not so much, the ability of the staff member but the *abstract concept* of the ability, attached to the relevant named procedure or task which is 'sitting there', waiting to be gained or not. Thus, there can be lists of 'competencies' which people need but haven't yet

obtained. For the sake of clarity these will be referred to as '**areas of competence**'.

The terms '**protocols**' and **'standard operating procedures'** are both in common use-the former more common in clinical situations and the latter in technical situations. They will be used in the measures to reflect these common uses but for the purpose of peer review, will be taken to mean the same thing-a description of what is agreed to be the correct way of carrying out a specific task or set of tasks.

Documentation.

Areas of competence can be classed and categorised in different forms and CCSs may collect and store training records in different forms. Review systems ask for evidence documentation in different forms. The terminology, below is not official, it's just for guidance.

i) **Individual training record**. The record relates to the individual and lists their competencies.
ii) '**Departmental' training record**. The list relates to an area of competence and lists the individuals with that competency in the department (or in this case, the CCS).
iii) '**Pathway stage'-specific, training record**. For an individual or a staff group it records whether they have the competencies associated with a certain stage of the pathway e.g. prescription, dispensing, administration. This would be across a range of cancer sites.

It seems from the above, that a service could sensibly make use of **all** those types of record. With computer- held staff data on spreadsheets, it should be easy to 'cut' the relevant information into whatever form it is needed for departmental use and for documentation of compliance for peer review.

Training and Assessment Policy

11-3S-116

There should be a CCS policy specifying the following:

- that it should cover the following professional groups (registered with statutory bodies) for their activities in the CCS; medical oncology, clinical oncology and haemato-oncology; nurses, pharmacists and pharmacy technicians;
  Note: Issuing and dispensing may be performed by suitably competent non registered personnel.
- that it should cover those activities specified in the lists of competencies, (measure 11-3S-118);
- that a member of one of those professions should have their current competence for that part of the process, assessed and documented in a training record before they may be considered capable of either of the following:
  i) independently delivering their profession's input into a given part of the process;
  ii) being a person who should be mandatorily present in a team of people inputting into that part of the process who otherwise might individually be at lesser degrees of training.
- that, in addition to the possession of documented competencies, the final responsibility for certain key activities should be restricted to certain of the professional groups, as follows:
  - Prescribing, verification, checking and administration should be restricted to statutorily registered health care professionals in medicine, nursing and pharmacy.
  - Clinical assessments and the decision to initiate the first cycle of a course of chemotherapy should be restricted to consultant medical staff and ST 3 and above medical trainee staff and NCCG medical staff who are assessed as competent for this by the training programme.

Compliance: The policy, agreed by the head of service.

Note: Compliance with this measure may be assessed at least in part by the parameters and practice governing the use of secure passwords into the service's computerised chemotherapy prescribing system.

Assessors of Competence

11-3S-117

There should be a single list of authorised assessors of competence for chemotherapy practice in the CCS together with the competencies they are authorised to assess; which fulfils the following:

- staff competency will only be considered valid if assessed by an assessor whose

name is listed at the time of assessment;
- entry on to the list and maintenance on the list is dependent on the authorisation of the head of service or person(s) designated by the head;
- a pre-requisite for authorisation is to meet the network criteria for assessors of competence.

Compliance: The current list, agreed by the head of service or the person(s) designated.

The reviewers should enquire as to the working practice of the CCS regarding the requirements for listing and its use in restricting who can be an assessor.

Notes: It is at the discretion of the relevant CCSs whether a given assessor may act for more than one chemotherapy service in the network, but there should be one list of assessors for the CCS under review.

A person may not authorise themselves as a listed assessor.

Named Areas of Competence

11-3S-118 The CCS should describe and list the areas of competence into which, the process of chemotherapy will be divided for the purpose of a competency-based training system.

The contents of each area (the relevant knowledge and skills) should be declared.

For each area of competence, it should state any objective criteria (e.g. qualifications from external bodies) which need to be fulfilled for awarding the documentation of competency in that area besides just the opinion of the CCS authorised assessor.

Notes:

- *There may not be any objective criteria necessary, for some areas.*
- *The areas of competency so defined should not include **degrees** of increasing ability during training but should confer the ability to practice fully **independently** (see measure 11-3S-116) and should refer to 'specific', 'technical' areas of competence rather than competence in generic communication skills and ability to assess patients' cultural, emotional and spiritual needs.*
- *Progressive levels of competence and holistic assessment are no less important but are dealt with elsewhere.*
- *Where nationally agreed requirements exist for defining what makes up a given area of competence, these should be adopted by the network. Until such national competencies are agreed for nurses administering chemotherapy, those specified for the Manual for Cancer Services, 2008, should be used and any competencies used by the CCS for medical staff administering chemotherapy should be drawn from them. These competencies from the 2008 manual are listed for information, in the appendix 1 to these current measures.*

The areas of competence and the contents of each should be agreed by the NCG.

Note:

This is a quality assurance device. The NCG should only agree the areas of competence if it considers them to be fit for purpose.

Compliance: The areas of competence and their content, with any associated objective criteria for assessment, agreed by the head of service and the Chair of the NCG.

Note: It would be easy to make this measure impossible to comply with because of the open-ended range of possible areas and their detailed contents. Reviewers are required to exercise judgement over whether this issue has been realistically addressed.

Training Records

11-3S-119 The department should keep training records which can be made available in the following forms:

- individual staff members' record (the current list of areas of competence for which the staff member is documented as competent by an authorised assessor);
- a departmental record of members of staff currently documented as competent by

an authorised assessor; for any given area of competence.

The department should use the training records, together with the professional group restrictions on practice (Training and Assessment Policy, measure 11-3S-116) to determine who and only who is authorised to carry out a given task in the department.

Compliance: Randomly chosen examples of training records of the following staff groups:

- a prescribing member of the medical staff;
- a nurse administering chemotherapy;
- a pharmacist working in an oncology pharmacy department;
- a pharmacy technician working in an oncology pharmacy department;
- if not covered by any of the above, (and if applicable to the department) a nurse assessing patients for chemotherapy (nurse-led clinic);
- if not covered by any of the above, (and if applicable to the department) a pharmacist assessing patients for chemotherapy (pharmacist-led clinic).

Randomly chosen examples of departmental training records.

The reviewers should check for the records being up to date (according to the network agreement on renewal of competency) and authorisation, of the records.

The reviewers should enquire as to the working methods of the chemotherapy service regarding the restriction of practice to those who are trained and competent and in the relevant professional group.

TREATMENT ALGORITHMS AND TREATMENT PROTOCOLS

Introduction

Each NSSG in consultation with the NCG should agree a set of site specific chemotherapy treatment algorithms for the network (see the definitions of treatment algorithms, regimens and protocols under 'nomenclature' in the introduction to the chemotherapy measures). This requirement is covered in the site-specific measures for each NSSG. There are measures relating to these treatment algorithms in section 1E-1s for the NCG and measures for the CCS in this section, below, relating to the algorithms and also to chemotherapy treatment protocols. Some illustrative examples of treatment algorithms may be found in the Appendix to these measures.

Agreed List of Treatment Algorithms

11-3S-120 The multi-professional team should agree the list of treatment algorithms for its service(s), compatible with the site-specific treatment algorithms produced by the NSSGs. It should be updated every 2 years against the network algorithms current at that time, and the updated version agreed again with the NSSGs.

Notes:

- *The list should cover all agreed chemotherapy for solid tumour oncology and haemato-oncology, for all cancer sites covered by the CCS.*
- *The intention is **not** to require a single mandatory regimen for each clinical indication. It is to prevent individual practitioners having unorthodox, obsolete and unpredictably varying practice, which is against the opinion of their peers within the network.*
- *The network algorithm for a particular clinical situation may have a number of alternative regimens of which the multi-professional team need only agree those which it intends to use in its service. The multi-professional team need only address those clinical indications which are applicable to the scope of its practice. The key requirement is that all the algorithms on the multi-professional team list are compatible with the NSSG agreed list.*
- *The NSSGs for their compliance should each produce their own algorithms and the multi-professional team for the CCS's compliance with this measure, should agree its service's list, compatible with the network algorithms from all the NSSGs which are associated with its practice.*
- *This exercise should include oral chemotherapy.*

Compliance: The local list for the year prior to the self assessment/peer review visit, agreed by the

chairs of the NSSGs and the head of service.

For CCSs operating for three or more years since the publication of the measures, the algorithms are needed from the first year, then the agreed updates every two years up to the self assessment/peer review visit.

Policy for Preventing Regular Deviation from the NSSG Agreed Treatment Algorithms

11-3S-121

The multi-professional team should agree the network policy for preventing regular deviations from the relevant network algorithm.

Note: The NCG should produce the policy for its compliance with measure 11-1E-103s and the local team should agree to abide by it for its compliance with measure 11-3S-121

The CCS should record, for review by the NCG, the instances of deviation from the relevant network algorithm.

They should record in each case:

- the regimen used or change in order of the regimens;
- the indication for the deviation.

Compliance: The written policy agreed by the Chair of the NCG and the head of service.

The record of the deviations.

Note: If there have been no deviations since the previous review or self assessment, this part of the measure should be considered to have been complied with.

Clinical Chemotherapy Service Treatment Protocols

11-3S-122

The multi-professional team should agree a set of treatment protocols which are associated with the CCS's list of treatment algorithms, to govern the delivery of chemotherapy by the service. The protocols should be updated bi-annually.

Notes:

- *At this level of detail, the treatment protocols are for use within the CCS and do not need to be agreed with the NCG, provided the regimens are compatible with the network agreed treatment algorithms. This latter point is dealt with by other measures.*
- *The protocols do not all need to be updated at the same time.*
- *This measure should include oral chemotherapy regimens.*

Each treatment protocol should specify the following information:

- cancer type;
- name of regimen and the therapeutic drugs used;
- therapeutic intent-palliative/adjuvant/neoadjuvant/radical, as applicable;
- doses of therapeutic drugs;
- routes of administration;
- number of cycles or whether this is indeterminate;
- length of cycle and number and timing of administrations within a cycle;
- tests required before starting a course and prior to an individual cycle;
- supportive drugs with each cycle;
- therapeutic drug dose modifications and their indications.

Compliance: The treatment protocols in place prior to the peer review visit/self assessment, agreed by the head of service.

They may be presented as hard copies or as part of a computerised prescribing system. In the latter case the validation methodology for incorporation of new regimens onto the system should be such that the protocols are agreed by the head of service.

For CCSs which are being reviewed or self assessed more than three years since the publication of these measures the initial protocols are needed then the agreed 2 yearly updates.

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE

GUIDELINES AND PROTOCOLS (Measures 11-3S-123 to 11-3S-125)

Notes:*The term 'protocol' here does not refer to chemotherapy treatment protocols which are specifically defined in the introduction to the chemotherapy measures and are dealt with in measure 11-3S-122*

All the guidelines/protocols in the measures below should be agreed by the head of service for compliance.

Guidelines and Protocols

11-3S-123 There should be guidelines/protocols on at least the following:

- cytotoxic administration techniques;
- the care of venous access devices used in the hospitals, including the treatment of line complications;
- the use of drug delivery devices;
- the use of devices to prevent alopecia;
- the use of haemopietic growth factors and patient support using blood and blood products.

Compliance: The written guidelines/protocols.

Guidelines and Protocols for Systemic Therapy Acute Oncology Presentations

11-3S-124 There should be guidelines/protocols on at least the following which are classified as systemic therapy related acute oncology presentations (measure 11-1E-104y)

- the recognition and treatment of cytotoxic extravasation;
- the recognition and treatment of allergic reactions including anaphylaxis;
- the recognition and treatment of neutropenic sepsis;
- the prevention and treatment of cytotoxic induced emesis;
- the prevention and treatment of stomatitis, other mucositis and diarrhoea.

Compliance: The written guidelines/protocols.

Hospital Guidelines and Protocols

11-3S-125 The guidelines/protocols on at least the following issues should be common throughout an individual hospital involved in the service, whether they involve solid tumour oncology or haemato-oncology.

- cytotoxic administration techniques;
- the care of those aids to venous access used in the hospital, including the treatment of line complications;
- the recognition and treatment of cytotoxic extravasation;
- the recognition and treatment of allergic reactions including anaphylaxis.

Compliance: The written guidelines/protocols.

For compliance, services encompassing only one of the subspecialties, solid tumour oncology or haemato-oncology, where both are practiced in a given hospital, should agree common information with the other subspecialty, and the reviewers should check for compatibility.

24-hour Telephone Advice Service

11-3S-126 The CCS should agree the minimum service specification with the network chemotherapy group and should specify in particular:

- the contact number(s) they will use;
- the specified staff they will provide and for which parts of a 24-hour rota;
- their locally applicable policy for instructions to patients and carers.

Note:

The CCS may agree to provide a 24-hour rota exclusively for their own service, or may contribute staff to a service shared with other CCSs. This is for agreement with the network chemotherapy group.

Compliance: The written specification agreed by the Chair of the NCG and the head of service with the local features as specified above.

Note:

The NCG, for its compliance with the network measure, should produce the specification and the CCS for their compliance with this measure, should agree with it and provide their contribution.

INFORMATION (measures 11-3S-127 to 11-3S-128)

Introduction

The information mentioned in these measures should be agreed by the head of service for compliance. The emphasis here is intentionally on information about complications of chemotherapy. There are other categories of useful information for patients, but they are dealt with elsewhere. The documentary evidence for compliance with these measures may be presented as part of wider-ranging information packs for patients.

Information for Patients on Complications of Chemotherapy

11-3S-127 There should be written information for patients and carers covering whom they should contact for advice, details of the 24/7 advice service (measure 11-3S-126), the action they should take and the symptoms that should prompt all this, with regards to at least the following complications of chemotherapy:

- neutropenic sepsis;
- cytotoxic extravasation;
- nausea and vomiting;
- stomatitis, other mucositis and diarrhoea.

A record of the information given to the patient should be recorded in the patient's notes.

Note:

Specific requirements apply to the following settings for chemotherapy, which have no accompanying 'acute oncology' arrangements:

- *services in hospitals with outpatient chemotherapy but no A&E, acute medical admissions or oncology beds. (Group 4 hospitals in the classification in Table 1 of Topic 3Y, in the Manual for Cancer Services-Acute Oncology);*
- *services in the community, outside a hospital setting.*

*For these settings, the information, given to patients should not make any mention of the service itself as a point to which patients might return in between scheduled appointments for help with complications of therapy or acute problems from their disease. Neither should the service be mentioned in any 'negative instructions' on this issue. The information should only make any mention of the points or services which they **may** contact or refer themselves to.*

These special requirements have sometimes been referred to as the 'Treat and Transfer' policy.

Compliance: The written information.

Reviewers should check the notes.

Reviewers should take note of the special requirements of the so-called 'Treat and Transfer' policy in the relevant settings.

It is recommended that it is available in languages and formats understandable by patients including local ethnic minorities and people with disabilities. This may necessitate the provision of visual and audio material.

Regimen Specific Information on Complications

11-3S-128 There should be written information for patients and carers covering information specific to the regimens on the service's agreed list, which has not been covered by the guidelines/protocols in measure 11-3S-127

Note:

It would be easy to make this measure impossible to comply with because of the open-ended range of possible information. Reviewers are required to exercise their discretion to judge whether this issue has been realistically addressed.

The existence of such written information is especially important, however,

regarding oral cytotoxic drugs being taken by patients at home.

Compliance: The written information.

It is recommended that it is available in languages and formats understandable by patients including local ethnic minorities and people with disabilities. This may necessitate the provision of visual and audio material.

Consent Form

11-3S-129 The consent form, which patients sign prior to starting a course of chemotherapy, should enable them to acknowledge that they have received written information on toxicities which include:

- the generic written information specified in measure 11-3S-127 and, if applicable,
- regimen-specificinformation as specified in measures 11-3S-128.

In the case of the regimen-specific information, the regimen should be specified on the document form.

The patient should be given a copy of the consent form.

Compliance: The consent form.

Reviewers to enquire of procedure to ensure patients are given a copy of the consent form.

Note:

It is recommended that the form is available in languages and formats understandable by patients including local ethnic minorities and people with disabilities.

Patient Experience Exercise

11-3S-130 The clinical chemotherapy service should have undertaken or be undertaking an exercise during the previous two years prior to review to obtain feedback on patients experience of the services offered.

The exercise should at least ascertain whether patients were offered:

- the information for patients (written or otherwise);
- assessment of their emotional, practical, psychological and spiritual concerns (holistic needs assessment);
- the opportunity of a permanent record or summary of a consultation.

Note:

The exercise may consist of a survey, questionnaire, focus group or other method.

There may be additional items covered. It is recommended that other aspects of patient experience are covered.

Currently for the purposes of peer review the exercise need only cover the activities of the outpatient chemotherapy service. Trusts may wish to include inpatients at their discretion.

Compliance: The results (complete or in progress) of the exercise.

Treatment Plan Copy to GP

11-3S-131 There should be a plan of the patient's treatment which should be sent to the GP. The plan should include details of:

- treatment regimen;
- treatment start date;
- planned duration;

- treatment intent-palliative, curative, adjuvant, neo-adjuvant, other.

Note

Some treatment situations are difficult to categorise being intended to prolong life or induce remission as much as to palliate symptoms, but not expected to cure e.g. some treatments for ovarian, small cell lung, and some haematological malignancies.

Compliance: The reviewers should enquire as to the working practice of the service, regarding this and, if necessary, see copies of example letters or e-mails.

Treatment Record Prior to Commencing a Course

11-3S-132 There should be treatment records for each patient fulfilling the following minimum criteria prior to the start of a course of chemotherapy:

- patient identification;
- weight, height, surface area;
- cancer type;
- treatment intention - palliative, curative, adjuvant, neo-adjuvant, other * (see note at end of measure);
- regimen and doses (including all cytotoxic chemotherapy drugs to be used and elective essential support drugs other than anti-emetics);
- route of administration (oral, IV, IV infusion, IM, SC);
- number of cycles intended;
- frequency of cycles and of administrations within a cycle;
- investigations necessary prior to starting the whole course;
- investigations to be performed serially during the course (to detect/monitor both toxicity and response) and their intended frequency;
- for palliative, curative and neoadjuvant treatments, i.e. any treatment other than adjuvant; the maximum number of cycles after which the response to treatment is to be reviewed prior to continuing the course;
- attendances managed by agreed non-medical staff e.g. nurse led attendances.

Note:

** Some treatment situations are difficult to categorise being intended to prolong life or induce remission as much as to palliate symptoms, but not expected to cure e.g. some treatments for ovarian, small cell lung, and some haematological malignancies.*

Compliance: Reviewers should examine examples of patients' chemotherapy records or the computerised prescribing programme.

Treatment Record Prior to Commencing a Cycle

11-3S-133 There should be treatment records for each patient fulfilling the following minimum criteria, prior to each cycle:

- the results of essential serial investigations applicable to that cycle (and prior to an administration within a cycle, if applicable);
- any dose modifications and whether or not they are intended to be permanent;
- any cycle (or administration) delays;
- any introduced support drugs not recorded under measure 11-3S-132;
- performance status;
- any toxicities following the previous cycle.

The World Health Organisation (WHO) system for grading performance status and Common Terminology Criteria for Adverse Events (CTCAE) for toxicity should be used.

Compliance: Reviewers should examine examples of patients' chemotherapy records, or computerised prescribing programme.

Treatment Summary

11-3S-134 There should be treatment records for each patient fulfilling the following minimum

criteria, after the final cycle is given in a course:

- whether the course was completed or not;
- if not completed - the reasons for cessation:
  o toxicity
  o sub optimal response (for non-adjuvant treatment);
  o disease recurrence during adjuvant treatment;
  o others, or combination of the above.

For completed courses of non-adjuvant treatment a reference to the response should be included.

A copy of this record should be offered to the patient and sent to the patients GP and any other relevant health care professionals.

Compliance: Reviewers should examine examples of patients' chemotherapy records, or computerised prescribing programme.

Reviewers should enquire of the process for ensuring copies are offered to patient and sent to the patient's GP and other relevant health care professionals.

The Chemotherapy Dataset

11-3S-135 The chemotherapy service should be electronically collecting the national chemotherapy dataset on its patients.

NOTE THIS MEASURE WILL BE INCLUDED FOLLOWING THE IMPLEMENTATION OF THE NATIONAL DATABASE IN 2012.

Compliance: The reviewers should enquire as to the working practice of the service and see examples of the dataset for individual patients, retrieved from an electronic database.

Workload Arrangement

11-3S-136 There should be an agreed arrangement whereby the head of service, in consultation with the oncology pharmacy service and lead chemotherapy nurse is able to limit the number of chemotherapy patients being treated when they judge the workload to have reached unsafe levels.

Note:

Factors which may be taken into account when estimating workload include complexity of regimens and availability of staff.

Compliance: The written arrangement agreed between the head of service, the lead chemotherapy nurse, the lead pharmacist(s) of the oncology pharmacies supporting the service, and the relevant hospital managers.

Chemotherapy Capacity and Scenario Planning

11-3S-137 The CPORT system for capacity and scenario planning should be used in the CCS.

Note:

CCSs who choose not to use the CPORT system should demonstrate use of a similar system.

Alternative systems may be manual rather than electronic.

Compliance: The reviewers should see the system in use for the CCS.

Out of Hours Chemotherapy

11-3S-138 There should be a policy for the CCS, agreed with the supporting oncology pharmacy service(s) and the relevant hospital manager(s), stating:

- in which, and only which, exceptional circumstances the administration of chemotherapy may be allowed outside "normal working hours";
- the arrangements for administering chemotherapy which then apply.

Notes:

The exact definition of "normal working hours" should be agreed locally as part of the policy.

It is widely accepted and strongly recommended that chemotherapy should, as far as possible, take place during normal working hours. It is more practical, however, from the point of view of a precise review measure, to define and agree the few exceptions to this rule.

Compliance: The policy agreed by the head of service, the lead pharmacist(s) of the supporting oncology service(s) and the relevant hospital manager(s).

ELECTRONIC PRESCRIBING

Computer Generated Prescriptions

11-3S-139 There should be a database driven, electronic prescribing platform in use which at least fulfills the following:

- it enables electronic prescribing using approved protocols;
- it provides an auditable record of chemotherapy, prescribed and administered; the record encompassing the proposed national mandatory chemotherapy dataset;
- it enables data extraction using Business Objects/Data Warehousing.

Compliance: The reviewers should view the output of the system and enquire of the working practice of the service.

STANDARD OPERATING PROCEDURES FOR ELECTRONIC CHEMOTHERAPY PRESCRIBING SYSTEM

Local Configuration of the Electronic Prescribing System

11-3S-140 There should be local configuration of the electronic prescribing system to allow electronic interfacing between and integration of, (i) patient demographics, (ii) laboratory test results and (iii) dispensing. This should enable the potential removal of manual transcription.

Note:

Compliance with this measure does not require the department to have actually removed manual transcription, yet.

There should be a procedure for the exceptional manual entry of laboratory test results and manual patient registration onto the system.

The procedure should be approved by the NCG.

Note:

This is a quality assurance device. The NCG should only agree the procedure if it considers it to be fit for purpose.

Compliance: The reviewers should view the output of the system and enquire of the working practice of the service.

The procedure, agreed by the lead clinician of the chemotherapy service and the chair of the NCG.

Consideration of Suggested Variations to the Use of the Electronic Prescribing System

11-3S-141 There should be a standard operating procedure (SOP) for the process of consideration of suggested new variations to the system's use, including new regimens and/or modifications of regimens.

The SOP should include specification of the categories of personnel with their minimum qualifications and/or competencies which should be mandatorily involved in the process.

Note: This measure is not referring to the process of accepting new regimens onto the list of treatment algorithms. This measure deals with the incorporation of regimens into

the electronic prescribing system.

Compliance: The SOP agreed by the lead clinician of the chemotherapy service.

Validation of the Incorporation of Individual Regimens Onto the Electronic Prescribing System

11-3S-142

There should be a SOP for the validation of the system's use with regard to individual regimens and /or modifications of regimens or protocol variations prior to their being first released for prescribing to patients.

The SOP should include specification of the following:

- validation of the system protocol against the local, agreed treatment protocol;
- validation of any drugs new to the system, included in the protocol. If drugs are set up locally this must be covered in the SOP;
- validation of the chemotherapy prescription generated, against local prescription formats and protocols;
- validation of the pharmacy worksheet generated, against local pharmacy protocols;
- the categories of personnel with any minimum qualifications and/or competencies which should be mandatorily involved in the validation process;
- the requirement that the validation process should be checked by a person(s) acting independently of the one(s) carrying out the initial incorporation into the system.

Compliance: The SOP agreed by the lead clinician of the chemotherapy service.

TOPIC 11-3S-2 - ONCOLOGY PHARMACY SERVICE

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE

The responsibility for review purposes for section 11-3S-2 lies with the head of pharmacy. The measures in this section should be applied to each individual oncology pharmacy service and the compliance counts as the review of that service

Lead Pharmacist

11-3S-201 The lead pharmacist should agree a list of responsibilities for the role with the lead cancer clinician(s) of the trust(s) involved in the service and the lead pharmacist's line manager.

Note:

See the notes below for the case where the lead pharmacist is the only designated pharmacist for the service.

Compliance: The list of responsibilities agreed by the lead cancer clinician(s) and the line manager.

DESIGNATED PHARMACIST

Introduction

The duties identified in measures 11-3S-203 and 11-3S-205 may be divided between more than one designated pharmacist. They need not be their only duties. The duties in measure 11-3S-204 should be assigned to a single designated pharmacist. Where the oncology pharmacy service under review has only one pharmacist, they should take the role of designated pharmacist as well as lead pharmacist, and should have all the duties of measures 11-3S-203 to 11-3S-205 in their list of responsibilities.

Designated Pharmacist

11-3S-202 There should be one or more named pharmacists for the service whose role is defined by the duties described in measure 11-3S-203 below. For review purposes these pharmacists are termed 'designated pharmacists'.

Note: The role of designated oncology pharmacist need not occupy the whole of a pharmacist's duties.

Compliance: The named designated pharmacist(s) agreed by the lead pharmacist.

Designated Pharmacist Duties

11-3S-203 The following duties should be included in the list of responsibilities of a designated pharmacist agreed by the lead pharmacist and the relevant line manager, for the CCSs declared as being supported by the pharmacy service under review:

- overall responsibility for oncology services to the named wards/areas/outpatient facilities used exclusively or preferentially for chemotherapy and aseptic procedures,specified in measures 11-3S-103 to 11-3S-104;
- overall responsibility for oncology services to the outpatient services specified in measure 11-3S-104 on the days they are used for chemotherapy;
- overall responsibility for cytotoxic chemotherapy;
- overall responsibility for clinical trials.

Compliance: The list of responsibilities of the relevant named designated pharmacist(s) agreed by the lead pharmacist and the relevant line manager.

Responsibility for Aseptic Chemotherapy Preparation

11-3S-204 The following duty should be included in the list of responsibilities of a single designated pharmacist:

- overall responsibility for the aseptic chemotherapy preparation facilities of the pharmacy service.

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE

Compliance: The list of responsibilities of the relevant named designated pharmacist agreed by the lead pharmacist and the relevant line manager.

Aseptic Preparation Audit

11-3S-205 The oncology pharmacy service should have been independently audited for at least the aseptic preparation of compounds, and the preparation of chemotherapy, and should have agreed to abide by its findings.

The audit should be conducted as follows:

- Licensed Units - Medicines and Healthcare Products Regulatory Agency inspection within two years prior to the self-assessment/peer review visit.
- Unlicensed Units - an external audit by the Regional Quality Assurance Pharmacist within eighteen months prior to the self-assessment/peer review visit.

The inspection/audit should identify any action, and any resulting proposals for investment should have been presented to the head(s) of the pharmacy department(s) of the host hospital(s) and to the relevant locality group.

Compliance: The results of the inspection or external audit and any action agreed by the lead pharmacist.

The reviewers should enquire if there were any investment proposals and if they have been presented to the head(s) of pharmacy and the locality groups.

VINCA ALKALOIDS

Introduction

The following measures reflect the National Patient Safety Agency Rapid Response Report NPSA/2008/RRR004 - Using Vinca Alkaloid Minibags. Also, the statements on the dilution of vinca alkaloids, presented in syringes are in accord with the advice from the DH current at the time of publication of this measure. In particular, following NPSA/2008/RRR04, and further discussions, it is acknowledged that paragraphs **78-80** of the ITC guidance, HSC**2003/010,** still apply.

Vinca Alkaloid Policy

11-3S-206 There should be a written policy that specifies that;

1. Vinca alkaloids should only be supplied to adult and adolescent services in the form of minibags. In this case the following points apply:

- The prescribed dose of vinca alkaloids should be supplied ready to administer in a 50ml minibag of sodium chloride 0.9% (for some brands of vinorelbine glucose 5% solution for injection may be used instead of sodium chloride 0.9%).
- All vinca alkaloid doses should be labelled **'For Intravenous Use Only - Fatal If Administered by Other Routes'.**
- There should be judicious use of colour and design on the label, outer packaging and delivery bags to further differentiate minibags containing vinca alkaloids from other minibag infusions.
- The vinca minibag should be infused intravenously over 5 - 10 minutes.

2. Children should not be treated in adult or adolescent clinical areas. In the unlikely situation that this requirement should arise, a local risk assessment should be undertaken to determine the safest method of intravenous vinca alkaloid treatment.

3. Vinca alkaloids should be supplied to children's services only in syringes. In this case the following points apply:

- For patients **over** the age of **10** years, the pharmacy should dilute the volume of intravenous **vincristine** to a maximum concentration of 0.1mg/ml and dispense it in a 10ml syringe as a minimum. For patients **over** the age of **10** years, the pharmacy should dilute the volume of intravenous **vinblastine, vindesine or vinorelbine** to a minimum volume of 20ml.
- For children **under** the age of **10** years intravenous **vincristine, vinblastine,**

vindesine or vinorelbine can be given at a higher concentration.

The only exception to this applies to **CCLG (Children's Cancer and Leukaemia Group) Centres**. These centres may choose, following a risk assessment, to give intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) to children of any age at concentrations higher than those specified above. However, this practice must be:

- covered by a waiver signed by the Chief Executive, Medical Director, Director of Nursing & Chief Pharmacist - a waiver template may be found in the appendix 1;
- addressed in the local ITC policy;
- covered in ITC induction and training programmes.

Note:

The correct interpretation of and compliance with this measure should result in any given chemotherapy service normally dealing with only one form of presentation of intravenous Vinca Alkaloids.

Compliance: The written policy agreed by the lead pharmacist(s) and heads of service of all the chemotherapy services supplied by the oncology pharmacy under review.

Reviewers to enquire of the working practice of the pharmacy with regards to this policy and inspect samples of dispensed vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) for IV use if possible.

If it is not possible to inspect samples, reviewers should inspect pharmacy dispensing records e.g. completed worksheets and copies of labels.

WAIVER TO THE NATIONAL GUIDANCE ON VINCA ALKALOID DILUTION IN SYRINGES

Introduction

If the host trust does **not** intend to give intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) at higher concentration than in measure. 11-3S-206, this measure does **not** apply. If it does apply, it is the responsibility of the ITC lead and lead oncology pharmacist and should be applied once for the trust. If the pharmacy service under review, supplies intravenous vinca alkaloids to chemotherapy services across more than one trust, there should be a discussion with the review team on the application of this measure as there may be a need for a waiver affecting part of the pharmacy's output.

Waiver to the National Guidance on Vinca Alkaloid Dilution in Syringes

11-3S-207 Intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) can only be used in the trust at concentrations higher than allowed in measure 11-3S-206 if all of the following are fulfilled.

- It is done only in the cases of children, and the chemotherapy service in question is part of a CCLG centre.
- A risk assessment of this practice in the trust has been carried out or the findings of a previous one have been reviewed in the year prior to the peer review visit, and the findings documented and then agreed by the trust CE.
- A waiver to paragraph 78 of HSC2003/010 has been signed or a previous waiver updated by signing by the Trust CE, Medical Director, Director of Nursing and Chief Pharmacist, in the year prior to the peer review visit, and sent to the relevant SCG.

Compliance: The risk assessment findings agreed by the trust CE.

The waiver agreed by those specified above. The reviewers should enquire of the SCG, whether a copy of the waiver has been sent.

TOPIC 11-3S-3 - INTRATHECAL CHEMOTHERAPY (ITC)

Introduction

All trusts in which intrathecal chemotherapy (ITC) is administered will be reviewed against the measures in this section which are additional to those in sections 3S-1 and 3S-2. The measures in this section are based on the guidance published in HSC2008/001. Trusts are reminded that while HSC2008/001 should be supplemented by additional local protocols, the HSC guidance must be applied in full and unchanged. Trusts which have declared that they do not administer ITC will not be reviewed, except against measure 3S-301 which requires a written policy on the action to be taken if, exceptionally the trust has to treat a patient for whom unplanned ITC is required urgently and transfer to an ITC trust is not possible e.g. if the patient is deemed too unwell to move. This is expected to be a rare occurrence.
Note that the compliance with the ITC section is attributed to individual trusts. This may not, in some cases, map simply onto cancer networks. Detailed advice for trusts and peer reviewers on how the ITC measures relate to the general chemotherapy measures in sections 3S-1 and 3S-2 is given in appendix A at the end of this introduction.

The Organisation of the Trust's ITC Service and its Implications for Review

A trust may encompass more than one hospital and ITC may be administered to different categories of patients in different hospitals and within different departments within a hospital. For the purpose of review against the measures, these parts of the trust's ITC service are termed 'divisions'. It is recognised that the term "division" may mean different things in different trusts. The term as it is applied here is used solely for the purpose of peer review and trusts locally can use a different term if they wish.
Each division of the trust's ITC service will be reviewed against the relevant part of the measures and will be required to comply separately with these measures. The different categories of patient in question here are:

- Adult, solid tumour oncology
- Adult, haemato-oncology
- Paediatric Oncology

The particular categories and how many of them, which are encompassed by a given division of the ITC service in the trust, is a matter for the trust to judge, as it deems appropriate to the distribution of services across the trust's hospitals. However, it should be subject to the following constraints which are similar to those applying in the general chemotherapy measures.

- There should be no more than one division of the ITC service for adult solid tumour oncology in a given hospital and no more than one division of the ITC service for adult haemato-oncology in a given hospital. If numbers of adult patients in either solid tumour or haemato-oncology are very small resulting in concerns about lack of experience/practice then a single division for adult services combining both solid tumour oncology and haematology should be considered.
- There should be no more than one division of the ITC service for paediatric oncology in a given hospital.

The trust may choose to have all of its ITC services reviewed as one undivided service but this has certain implications. For example, the details of the written checking procedure (measure 11-3S-321) and the out of hours working policy (measure 11-3S-322) would need to be the same throughout all hospitals of the trust. Each division of the ITC service as declared and put forward for review by the trust, will be reviewed as one entity e.g. all of the non-registered staff involved in that division of the service should have read the ITC guidance and local protocol, for that division of the service to comply.

The trust is required to appoint a single overall lead for ITC, who may delegate responsibility for named ITC divisions to named individuals, and may delegate responsibility for training to a named ITC training lead.

A number of measures apply trust wide. These will be applied once for the trust, under the direct responsibility of the ITC lead. e.g. there should be a single register of authorised and competent practitioners for ITC, for the trust (measure 11-3S-308). The measures assume that a trust will have a pharmacy service that can be considered as a single managerial entity and that pharmacy-related policies can be agreed to apply trust wide. The pharmacy related measures will be reviewed as being under the responsibility of the ITC lead. Where there are a number of pharmacies in different hospitals of the trust, which are involved in the ITC service, a measure which is relevant to a pharmacy will be applied separately to, and compliance recorded separately for, each individual pharmacy. The term "pharmacy" is used throughout this document for simplicity - it is recognised that trusts may recognise this by some other name such as dispensary.

APPENDIX A

Notes on Integration of the Intrathecal Chemotherapy Measures (3S-3) with the General Measures on Chemotherapy (3S-1 and 3S-2)

Organisation of the service

It is recommended that the divisions of the ITC service map, if possible, on to the general clinical chemotherapy services of the network, provided this is compatible with the ITC measures themselves. e.g. If a hospital has a combined solid tumour oncology and haemato-oncology, clinical chemotherapy service, it should consider having a combined division of the ITC service, which deals with the cases arising from both areas of practice.

Clinical Leadership

The trust lead for ITC and the named persons with delegated responsibilities (11-3S-302) may or may not be the same people as are heads of service of general chemotherapy services in the trust. Assessors of competency for ITC administration (11-3S-311) may or may not be the same people as competency assessors for general chemotherapy administration, provided the relevant measures are fulfilled in each case.

Training

Induction and training for ITC chemotherapy tasks may or may not be delivered as part of the same local training programme which deals with general chemotherapy provided it can be separately verified that a given member of staff has received general or ITC-specific training in line with those measures.

General Quality Measures, applied to ITC

The practice of the ITC service, as well as being subject to the measures in 11-3S-3 (derived from the specific ITC national guidance on safe practice), should not be ignored from the point of view of the general quality measures which are required of the rest of the hospital's chemotherapy practice. The ITC service should be associated with a clinical chemotherapy service and a relevant head of service. Reviewers should note when reviewing that general service, whether the following measures are fulfilled for the associated ITC service:

- Provision of Protocols and Equipment (11-3S-105) - applied to ITC areas
- Treatment protocols (11-3S-120) - applied to the ITC regimens
- Guidelines/protocols (11-3S-123, 11-3S-124,) - applied to ITC.
- Record of treatment (11-3S-132 to 11-3S-134) - for ITC procedures.

The rest of the measures in 3S-1 should be applied only to the general, clinical chemotherapy service. It is recommended that pharmacists on the ITC register will be chosen from the 'designated pharmacists' of the relevant oncology pharmacy service of the network. The results of the application of the above measures from 11-3S-1, to an associated ITC service, count towards the peer-review result of the relevant general clinical chemotherapy service.

TOPIC 11-3S-3 - INTRATHECAL CHEMOTHERAPY (ITC)

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE

The responsibility for review purposes for measures 11-3S-301 to 11-3S-302 lies with the CEO of the trust(HSC2008/001 para 16).

Management and Organisation

11-3S-301

The trust should declare whether it has an ITC service, or whether it is to be designated a 'non ITC' trust.

If the former, the rest of this measure is not applicable, and the trust should then be reviewed against the rest of the ITC measures.

If the latter, the trust should have a written policy to the effect that ITC should only be administered in the trust when the following apply:

- it is considered impossible or impractical to move the patient in time;
  and
- the treatment is urgent;
  and
- the decision to treat with ITC in the trust is taken in consultation with the host trust Medical Director, CE and an ITC registered consultant from another trust, which is an ITC trust;
  and (if time allows)
- in consultation with the non - ITC trust's SHA;
  and (whenever possible)
- the ITC administration is carried out or supervised by ITC registered personnel from the ITC trust referred to above;
- following such an administration, (i) documentation is provided on why it had to take place, the remedial actions taken and the outcome; (ii) the documents are reviewed according to the trust's risk management arrangements; (iii) the SHA is informed (if not informed prior to the administration).

The policy should be distributed to all consultant medical oncologists, clinical oncologists, paediatric oncologists, haemato-oncologists and the Chair of the Drugs and Therapy Committee.

Note:

This is the only measure that applies to a non-ITC trust.

Compliance: The declaration agreed by the trust CE.

The policy, agreed by the trust CE, Medical Director, Director of Nursing and Chief Pharmacist.

The reviewers should enquire of the distribution process.

Single ITC Lead

11-3S-302

There should be a single ITC lead, designated for the trust.

They should have an agreement with the trust CE that they are accountable to the CE for compliance with the national ITC guidance and these measures (HSC 2008/001 para16).

Notes:

If the ITC lead delegates individuals for named tasks, this should be specified in the agreement.

The ITC lead should be one of the following:

- consultant medical oncologist;
- clinical oncologist;
- paediatric oncologist;
- haemato-oncologist;
- nurse on the ITC register;
- pharmacist on the ITC register.

Compliance: The named designated ITC lead, agreed by the trust CE.

The accountability agreement authorised by the trust CE.

The responsibility for measures 11-3S-303 to 11-3S-322 lies with the trust ITC lead

ITC Service Divisions

11-3S-303

The divisions, into which the trust's ITC service is divided, for review against the measures, should be declared, naming the hospitals and categories of patient which are encompassed by each division. (See the introduction to the ITC measures).

Note:

The trust may choose to have all of its ITC service reviewed as one unified service (in effect, as one division). This should be declared, naming the hospitals and patient categories which are encompassed.

If the ITC lead delegates named individuals to be responsible for named divisions of the service and/or a named ITC training lead for the trust, these should be declared.

Each delegate should have agreed a list of responsibilities with the trust ITC lead.

Notes

If the ITC lead chooses to be directly responsible (without delegation) for certain named divisions of the service and/or for training, this should be declared.

The delegated individuals should each be one of the following: consultant medical or clinical oncologist; paediatric oncologist; haemato-oncologist; nurse on the ITC register or pharmacist on the ITC register.

Compliance: The list of divisions of the service, naming the hospitals and categories of patient, agreed by the ITC lead and the trust CE.

The named delegates (or ITC lead) with the named division(s) or training for which they are responsible.

The list of responsibilities for each of the named delegates.

Case Volume and Risk Assessments

11-3S-304

The number of ITC administrations performed in the trust per year, averaged over the 2 years prior to the self assessment/review visit, should be recorded.

If the number of administrations per year, recorded as above, is 10 or less (low volume) there should have been a risk assessment carried out on the ITC service with respect to safety issues associated with having a low volume service, and with respect to the ITC guidance.

- The results and any action arising should have been discussed and agreed with the

trust CE.
- The decision to continue the service should be agreed by the trust CE.

If the number of administrations per year, recorded as above, is 500 or more (high volume), there should have been a risk assessment carried out on the ITC service with respect to the safety issues associated with having a high volume service and with respect to the ITC guidance.

- It should include a locally agreed, maximum safe workload level and actions to address any capacity increase should this be needed to avoid exceeding the agreed maximum workload.
- The results and any action arising should have been discussed and agreed with the trust CE.

Notes:

If the number of administrations per year, recorded as above is more than 10 and less than 500, then a risk assessment is not required. ITC leads and/or trust CEs may, of course, still carry out risk assessments at their discretion, but these are not subject to the peer review.

The actual results of the risk assessment and the nature of any actions agreed are not subject to review.

Compliance: The number of ITC administrations agreed by the trust ITC lead.

If applicable:

The results, decision and any required actions of the risk assessment, agreed by the trust CE and the ITC lead.

Note:

Agreed extracts or summaries would be compliant, sufficient to show that the risk assessment took place and any necessary action agreed.

Local Protocol

11-3S-305

There should be a single, written, local (i.e. trust) protocol covering the national ITC guidance, which clarifies how the guidance applies specifically to the trust's own ITC service. It should specify:

- **who**, in terms of named personnel and/or posts in the trust, is permitted to carry out tasks involved in ITC as specified in the guidance(HSC2008/001 para 21);
- **where**, in the trust, in terms of named divisions of the ITC service, hospitals, wards, departments, pharmacies, designated areas and physical facilities, specified tasks are permissible;
- **where** in the trust, (as above), copies of the key documents specified inthe ITC guidance, may be found.

Notes:

Information in the local protocol about intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) should be kept separate from information about ITC wherever possible.

The local ITC protocol should not change any elements of the national ITC guidance.

The local ITC protocol may form part of the local protocols relating to the general chemotherapy service.

The local protocol should state where copies of the trust ITC register can be found. (see measure 11-3S-306).

The local ITC protocol should specify any waivers to the national guidance applying to the trust (see measures 11-3S-207 & 11-3S-312).

Compliance: The local protocol, agreed by the ITC lead managers of the departments mentioned in it, any delegated individuals.

The contents of the local protocol as it deals with individual aspects of the ITC guidance,

and whether it exhaustively covers the whole guidance, should not be reviewed in detail under this measure, since the individual aspects are covered by the subsequent ITC measures.

Distribution of the Local Protocol and Guidance

11-3S-306

There should be hard copies of the local protocol and the national ITC guidance in at least the following locations in the trust:

- all areas where ITC is dispensed, issued or administered;
- all wards (oncology in-patient area) where oncology/haemato-oncology patients are admitted, even if not used as ITC areas.

There should be a method for the trust, designed to ensure that the hard copies of the national ITC guidance and the local protocol lodged in the locations are kept up to date.

If the local protocol and/or ITC guidance is maintained in electronic form on the trust intranet, there should be a method designed to ensure that these documents are kept up to date as displayed on the intranet.

Note: An electronic form does not preclude the requirement for hard copies as above.

Compliance: The reviewers should enquire of the distribution process for hard copies and view the locations.

The reviewers should enquire of the method of updating both the hard copies and the electronic versions and view the documents on the intranet.

Lead Trainer

11-3S-307

There should be an ITC lead trainer for the trust, either the ITC lead or a named individual delegated with the responsibility by the ITC lead.

They should be drawn from one of the following: consultant medical oncologist or clinical oncologist, paediatric oncologist, haemato-oncologist, nurse on the ITC register or pharmacist on the ITC register.

The lead trainer should have agreed a list of responsibilities (which should include the implementation of the training policy) with the ITC lead or if the latter is acting as the lead trainer, with the trust CE.

The lead trainer should have agreed a minimum time available for the responsibilities in the weekly timetable.

Compliance: The named ITC lead trainer agreed by the ITC lead or, if the latter is acting as lead trainer, agreed by the trust CE.

The list of responsibilities and specified minimum time agreed by the ITC lead, or trust CE.

Note:

The actual time is not subject to review.

IT Register

11-3S-308

There should be a register for the trust of named personnel who are trained and certified competent to participate in ITC tasks. The register should fulfill the following criteria:

- There should be a single register for the whole trust, made up of different parts for different tasks, as specified below. Copies of these parts may be kept in separate locations, but for each task there should be a unique list of registered personnel, each list being a distinct part of the register.
- It should cover the following separate tasks, making up the entire ITC process:
  - prescribing ITC;
  - verification of ITC - prescriptions;
  - dispensing ITC drugs;
  - checking and issuing ITC drugs from the pharmacy;
  - checking ITC drugs prior to administration;
  - administering the ITC.

Note: A given person may appear as registered for more than one task, but the register should specify all the named staff who are competent for each task.

- The register should be updated at least annually or more frequently as required by changing personnel.
- Hard copies of the register should be distributed to, at least, all locations in the trust where the ITC is dispensed, issued or administered including oncology in-patient areas.
- Only up-to-date copies of the register should be lodged in each location

Compliance: The register, each part authorised by the ITC lead or the single person named by the ITC lead as having responsibility for authorising that part of the register. The reviewers should verify by inspection that different copies form part of a single register.

The reviewers should enquire of the distribution process for hard copies and view the locations.

Registration Procedures

11-3S-309 The following procedures regarding registration should be incorporated in the local protocol:

- Only those staff members named on the trust's own register for a given task in the ITC process are permitted to perform that task in the trust, except for the sole condition specified under the next bullet point.
- Personnel may perform a given task under constant direct supervision of personnel who are agreed as trust competency assessors for that task, see measure 11-3S-311, when it is being performed as part of the trust ITC registration training programme, competency review or refresher training.
- Only those staff members who have been trained and assessed as competent in that task, according to the trust's ITC training procedure, are eligible to be registered for that task.
- Only medical staff in the following categories (following training and the attainment of competence) are eligible to be registered for **prescribing ITC**; Consultants, Specialist Registrars (ST3), Associate Specialists. Individual Staff Grade doctors can also (following training and the attainment of competence) prescribe ITC if they have been named, and given personal written permission, by the Trust CE.
- Only medical staff in the following categories (following training and attainment of competence) are eligible to be registered to **administer ITC**; Consultants, Specialist Registrars (ST3), Associate Specialists, and Staff Grade doctors.
  Note:
  (i) FT1 and FT2 medical staff should never administer ITC.
  *(ii) ST1and ST2 medical staff can only be registered to **administer** ITC (following training and attainment of competence) if the trust has fulfilled the ST1/ST2 waiver measure - see measure 11-3S-312.*
  *(iii) ST1/ST2 can never be registered to **prescribe** ITC.*
  (iv) Radiologists who position lumbar puncture needles are not permitted to perform any other part of the ITC process or procedure.
- The registration status of any registered staff member never lasts for more than 1 year. Their name is deleted from the register unless their competence is reviewed and re-certified within that time. Re-certification may be dependent on refresher training.
- All staff should have the frequency with which they perform the registered tasks monitored and their competency reviewed annually by a named competency assessor.

The following procedures regarding holding and maintaining the register should be incorporated in the local protocol:

- Only the ITC lead or the single named person with responsibility delegated by the ITC lead for a specified part of the register, can authorise the entry of an eligible

person onto that part of the register for that respective task.

- If applicable, the people delegated to have responsibility for authorising entry onto the register for specified tasks, should be named in the policy, against the respective tasks.
- At their annual review of competence, or at any other time, the ITC lead, or a delegated person is authorised to delete a staff member from the register, if they are assessed as performing their registered task(s) insufficiently often to maintain competence.
- The initial assessment of competence and its annual reconfirmation includes there being written confirmation that the staff member has read the ITC national guidance and associated local protocols.

Compliance: The local protocol.

INDUCTION AND TRAINING

The responsibilities for measure 11-3S-310 lies with the lead trainer. It should be applied once for the trust.

Note:

A DVD to support local induction/training programmes in the safe administration of intrathecal chemotherapy is available from Department of Health Publications dh@prolog.uk.com . This DVD was produced to support the original guidance. Although the updated guidance has changed in some respects, the general messages in the DVD hold true. Additional information on using the training film can be found by searching "intrathecal chemotherapy training" on the Department's website: http://www.dh.gov.uk

Training Policy

11-3S-310

The trust should have an agreed training policy for ITC. The policy should specify that:

- all new staff to be incorporated on the ITC register(nursing, pharmacy and medical - including consultants) attend a formal induction course appropriate to their proposed role in the intrathecal chemotherapy service:
  - prescribing ITC;
  - verification of ITC prescriptions;
  - dispensing ITC drugs;
  - checking and issuing ITC drugs from the pharmacy;
  - checking ITC drugs prior to administration;
  - administering the ITC.
- the induction should in addition include:
  - all potential clinical hazards associated with intrathecal chemotherapy including the danger posed to patients if intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are accidentally administered intrathecally;
  - new safer practice recommendations from the NPSA on the presentation of intravenous vinca alkaloids for adults and for young people in an adult or dedicated teenage setting.
- staff involved in prescribing, verifying, dispensing, issuing, checking or administering intrathecal chemotherapy should read the national guidance and associated local protocols, and be required to sign a written confirmation that they have read and understood these documents before being allowed to practice their respective roles, this signed confirmation should be updated annually;
- all such staff should have their current competence assessed and documented in a training record for the roles they will be expected to undertake in providing an intrathecal chemotherapy service prior to being entered on the register;
- this competence will be reviewed annually alongside how often staff carry out this procedure for ITC. Re-certification of competence may be dependent on refresher training;
- all staff involved with the care and treatment of patients receiving ITC (not just those on the register) are informed of their responsibility for, and the process for, reporting colleagues if either protocols are not being adhered to or the actions of an individual may cause potential risk to a patient;

- all staff involved with the care and treatment of patients receiving ITC (not just those on the register) are informed of their responsibility for ensuring that any colleagues involved in this process are on the register for the task in question;
- All staff on the register should receive a certificate, or other written confirmation, that they have completed the induction course or, if applicable, annual refresher training and are competent/ remain competent to be included on the register for the designated task(s).
  Note: This policy should be implemented in addition to the general chemotherapy Training and Assessment policy measure 11-3S-116 and Training Records measure 11-3S-119

Compliance: The policy agreed by the lead trainer and the ITC lead or, if the latter is acting as lead trainer, the trust CE.

Reviewers to enquire of working practice regarding this policy and view examples of training records.

Named Competency Assessors

11-3S-311 There should be named competency assessors for the trust, specific for the register of ITC tasks as set out in measure 11-3S-308. They, and only they, should be permitted to assess and reconfirm the competency of staff seeking inclusion on the register. They should have fulfilled the following criteria:

Either:they have been through the trust's agreed training programme and have themselves been assessed as competent by it for the tasks which they assess;

Or:(for those who were the initial assessors of competence for the trust) they have been deemed competent directly by the ITC lead.

Compliance: The named competency assessors and for which specified tasks.

Confirmation of training or status as initial assessor of competence agreed by the lead trainer.

The reviewers should enquire as to the trust's practice of competency assessment.

WAIVER TO THE NATIONAL GUIDANCE ON ADMINISTRATION BY ST1 OR ST2 MEDICAL STAFF

Introduction

If the trust does not intend to allow ST1 or ST2 medical staff to administer ITC, the following measure does not apply. If it does, it is the responsibility of the ITC lead and should be applied once for the trust.

Administration by ST1 or ST2 Medical Staff

11-3S-312 If ST1 or ST2 grade doctors administer ITC in the trust, this may only be done if all of the following are fulfilled:

- the trust is not a 'low volume' ITC trust, see measure 11-3S-304;

Note

The spirit of the ITC guidance on this matter is that the waiver is used in only that minority of trusts where the ITC caseload enables ST1 or ST2 medical staff to have sufficient experience to gain and maintain competence in the administration of ITC. In practice it is unlikely that this will be considered safe unless the number of ITC procedures performed annually is considerably more than the 'low volume' threshold of 10.

- a risk assessment of this practice in the trust has been carried out or the findings of a previous one have been reviewed in the year prior to the self assessment/peer review visit, the findings documented and agreed by the Trust CE;
- a waiver to the national guidance prevention of ST1/ST2 grades from administering ITC has been signed or a previous waiver has been updated by signing by the trust CE, Medical Director, Nurse Director and Chief Pharmacist in the year prior to peer review visit and sent to the SHA Medical Director;
- an amendment has been made to the local protocol, to the effect that only those

named ST1/ST2 staff registered as fully trained and assessed as competent may administer ITC for the trust.

For trusts that have been allowing registered ST1/ST2 to administer ITC for 2 or more years since the publication of the national ITC guidance, the risk assessment findings should have been reviewed annually by the trust CE and the waiver reconfirmed annually if still appropriate.

Compliance: The reviewers should enquire as to the practice of the trust, and note the results for measure 11-3S-304

The risk assessment findings agreed by the Trust CE.

The waiver agreed by those specified above. The reviewers should enquire of the SHA.

The local protocol.

MANAGING INTRATHECAL CHEMOTHERAPY DRUGS

The responsibility for measures 11-3S-313 to 11-3S-322 lies with the ITC lead and they should be appliedseparately to, and compliance recorded separately for each pharmacy in the trust.

Storage in Pharmacy

11-3S-313 There should be storage facilities in the pharmacy for ITC drugs if needed for the time between dispensing and issuing of ITC drugs, which fulfill the following:

- they should be lockable;
- they are always available;
- they are only ever used for ITC drugs and this is made clear.

Note:

These should ideally be in the pharmacy.

Negative signs (i.e. "Not for ... use") should not occur on or in relation to the storage facility.

Compliance: The reviewers should view the facilities and enquire as to the working practice of the pharmacy.

Issuing of ITC drugs

11-3S-314 When issuing ITC drugs, it should be carried out only in one of the following ways:

Either:

Physically handed over in the pharmacy to the doctor who will be administering the ITC on the ward. (In this case this doctor is referred to as 'the collector').

Or:

Taken by a designated member of the pharmacy staff, whose name appears on the register, to the ward where the ITC will be administered and there, physically handed to the doctor who will be administering the ITC or placed by the member of the pharmacy staff into a designated storage facility as specified in measure 11-3S-319.

Note:

This is distinct from the storage facilities in the pharmacy, specified at measure 11-3S-313.

There should be a clear record (signatures) that the named issuer released the drugs from the pharmacy. Or, if relevant, there should be a clear record (signature) that the named issuer placed them into the designated storage facility specified in measure 11-3S-313.

When issuing an individual dose of ITC drugs from drugs which have been

produced in a batch, each individual dose should be separately dispensed and issued and separately signed for by the issuers before they are released from the pharmacy or separately signed into the designated storage specified in measure 11-3S-313.

Compliance: The reviewers should enquire of the working practice of the pharmacy.

Sequencing IV and IT Chemotherapy

11-3S-315 There should be written confirmation that all intravenous chemotherapy for a given patient for a given day, has been administered to that patient before any ITC drugs for that patient are issued by pharmacy for administering on that day.

Where a regime involves ITC combined with continuous intravenous Chemotherapy there should be written confirmation that IV infusion has already begun before ITC is issued from the pharmacy.

Note:

The only exceptions to this sequencing of intravenous before intrathecal chemotherapy are where it is a specific requirement of the regimen.

Compliance: The reviewers should enquire as to the working practice of the pharmacy and spot check the records of randomly selected ITC procedures including combined ones with continuous intravenous chemotherapy.

Labeling of ITC drugs

11-3S-316 There should be a written policy in the local protocol for the pharmacy department and implemented in each cytotoxic reconstitution unit to the effect that, for labels on individual doses of ITC drugs, the following apply:

- they should clearly show the patient's name and the name of the product;
- the route of the administration should be clearly printed in the largest font size possible and emboldened;
- negative labeling (i.e. "Not for ... use") must never be used.

Compliance: The written policy in the local protocol.

The reviewers should enquire as to the practice of the pharmacy and inspect randomly selected doses of ITC drugs if possible.

If it is not possible to inspect randomly selected doses, reviewers should inspect pharmacy dispensing records e.g. completed worksheets and copies of labels.

MEASURES FOR THE DECLARED DIVISIONS OF THE ITC SERVICE

Introduction

These measures deal with the activities of the medical and nursing staff in the divisions declared in measure 11-3S-303, with respect to the categories of patient which are also declared in measure 11-3S-303. All these measures should be applied to each division separately and the compliance recorded for each division separately. The measures cover the following subjects:

Certain aspects of induction and training, prescribing ITC, patient consent, collection and storage of issued drugs, checking and administering ITC. The responsibility for these measures lies with the ITC lead or the individual delegated by the ITC lead with responsibility for that division of the ITC service (see measure 11-3S-303). They are referred to as the 'responsible person for the division'. The exceptionto this is the measure on the induction and updating on non-registered staff which is the responsibility of the lead trainer.

In the unlikely situation where more than one declared division of the ITC service share some aspect e.g. a designated area for administering ITC, the common evidence for compliance would confer compliance on each division involved, but the reviewers should still record the results of the review separately for each division.

ITC Prescription Chart

11-3S-317 There should be a purpose-designed ITC prescription chart. This may be a chart uniquely for ITC, separate from the general chemotherapy chart, or a dedicated area on the general chemotherapy chart uniquely reserved for recording ITC.

There should be areas on the chart for people to authorise, by their full signatures, that they have carried out the following tasks:

- prescribing;
- issuing;

- collecting/delivery;
- checking by the administering doctor and another health care professional on the ITC register.

There should be areas for the drug and route of administration to be clearly indicated in full.

Electronic prescribing methods should achieve the same level of security and specificity of authorisation of tasks as in the above requirements.

Compliance: The prescription chart.

The reviewers should satisfy themselves that any electronic prescribing solution fulfills the requirements above.

Collection of ITC drugs

11-3S-318 The collection of a dose of ITC drugs from the pharmacy should be carried out in one of the following ways only:

Either, it should be handed over directly to the administering doctor.

Or, it should be collected by the administering doctor from the designated storagefacilities outlined in measure 11-3S-313.

Note:

The administering doctor is the doctor who is going to administer that particular dose of ITC.

When a dose of ITC drugs is collected from the issuer, there should be a clear record (signature) that the named administering doctor was given and received them, ***or***, if relevant, there should be a clear record (signature) that the named administering doctor collected them from the facility dedicated for storage of ITC drugs between issuing and administration and when they did so.

When an individual dose of ITC drugs is received from the issuer from drugs which have been dispensed in a batch, each individual dose should be signed for when collected from the issuer or as collected from the designated storage facilities, and when it was collected recorded.

Compliance: The reviewer should enquire as to the working practice of the division and spot check the records of ITC procedures when drugs have been issued in batches if possible.

Storage Outside Pharmacy

11-3S-319 There should be a facility available outside the pharmacy for the division of the service for the storage of ITC drugs between issuing and administration, if administration has to be delayed.

The facility and its use should fulfill the following criteria:

- it should be kept locked except for the depositing or withdrawal of ITC drugs;
- the key should be kept with the nurse in charge;
- it should be used exclusively for ITC drugs stored between their being issued and administered. This should be clearly indicated.

Note:

Negative signs (i.e. "Not for ... use") should not occur on or in relation to the storage facility.

Compliance: The reviewers should enquire as to the working practice of the division and should inspect the facility.

Designated ITC Room

11-3S-320 There should be a designated room or rooms for the division of the service, where ITC chemotherapy is given which should fulfill the following criteria:

- when intrathecal chemotherapy is being administered the designated room should not be used for **any other purpose**. Under no circumstances should any other form of **chemotherapy** take place in this room during that whole session;
- chemotherapy drugs for IV use may never be stored in the area even when it is not in use.

Compliance: The specified area(s) agreed by the responsible person and the relevant hospital manager.

The reviewers should enquire as to the working practice of the division of the service and view the area(s).

ITC Checking Procedure

11-3S-321 There should be a written ITC checking procedure for the division in the local protocol, which specifies the following:

- the checking of drugs prior to their ITC administration, as specified below, should only be done by staff who are registered for that task-the exception to this is, if desired, by patients or their parents or guardians as specified in the 4th bullet point;
- it ensures that the correct drug at the correct dose is to be given to the correctly identified patient by the correct administration route, prior to administration;
- it is carried out by at least the following staff members: the registered doctor who will be administering the ITC and another health care professional registered for the checking of ITC;
- it allows and offers the opportunity for the patient or, if relevant (e.g. in the case of patients who are minors), the parent, or guardian of the patient, to take part in the checking process if they so desire. (If the patient/parent/guardian has expressed this desire, an additional check to the minimum specified above, should be made by the senior theatre nurse when ITC is given under GA in theatre as the parent or guardian is normally unable to participate).
- the checks made are recorded.

Compliance: The written procedure, as part of the local protocol. The reviewers should enquire as to the working practice of the division and inspect the records of randomly selected ITC procedures.

ITC Administration within Normal Working Hours

11-3S-322 There should be a written policy for the division designed to ensure that ITC is administered within normal working hours wherever possible. It should fulfill the following:

- normal working hours should have an agreed local definition for the purposes of this policy;
- the exceptional circumstances in which ITC may be administered outside this definition of normal working hours should be specified;
- the special authorisation procedure (which should be over and above normal procedure) which is then necessary to allow it should be specified in line with the guidance.

Following such administration:

- A record should be kept, specifying each out of hours administration, enabling their frequency to be monitored.
- Documentation should be provided on why each had to take place out of hours, the remedial action taken and the outcome.

Compliance: The written policy agreed by the responsible person, the head of service of the relevant clinical chemotherapy service and the relevant hospital manager.

The reviewers should examine the record of out of hours ITC administration (if any have been performed) and examples of the documentation of an individual administration if relevant.

TOPIC 11-6A-1s - CHEMOTHERAPY MEASURES FOR PCTs

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE	
The responsibility for review purposes for this measure lies with the cancer clinical lead of the PCT.	
PCT Chemotherapy Policy	
11-6A-101s	The PCT should adopt a policy which specifies that general practitioners (GPs) should not prescribe systemic, including oral, cytotoxic chemotherapy, or intracavitary cytotoxic chemotherapy for the treatment of malignant disease when acting under direct contract or SLA with the PCT. The relevant contracts and/or SLAs should be consistent with this policy. *Notes:* *This does not apply to;* *(i) GPs who are acting for that part of their practice under contact to a hospital Trust;* *(ii) the prescription of oral hydroxy-carbamide, for cases under the overall care of a hospital consultant haemato-oncologist;* *(iii) the prescription of topical cytotoxic agents used for the treatment of some skin malignancies or premalignant conditions.*
Compliance:	*The policy, agreed by the cancer lead for PCT.* *The reviewers should enquire as to the working practice of the PCT regarding their contracts and SLAs.*

TOPIC 11-1C-1 - GENERIC CHEMOTHERAPY MEASURES FOR NSSGs

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE

CHEMOTHERAPY TREATMENT ALGORITHMS

Introduction

- For the purposes of peer review, a chemotherapy **regimen** is defined by the therapeutic chemotherapy drugs used, often expressed as an acronym e.g. 'FEC'. A change of one or more of these drugs themselves would normally be necessary for it to be classed as a change of regimen. In some cases major changes in the dose or route of administration of one or more of the drugs effectively changes the regimen but these cases are generally known and recognised nationally. A given network is free to choose any further changes which they classify as changing the regimen, as long as it is in accord with the above definition and national exceptions; i.e. they are free to make the definition of a regimen narrower, but not wider.
- For the purposes of peer review, a chemotherapy **treatment protocol** is defined as constituting all the parameters specified in the bullet points in chemotherapy measure 11-3S-122 A change in any of these parameters would change the treatment protocol but any change other than the therapeutic drugs themselves (apart from the national and local exceptions specified above) would change only the protocol, not the regimen as well.
- For the purposes of peer review a chemotherapy **treatment algorithm** may be described as a guideline which specifies the acceptable ranges of regimen options for named steps on the patient pathway. Treatment algorithms are cancer site-specific. They are not specific to individual patients, i.e. they are not individual treatment plans. Thus, a treatment algorithm for breast cancer would include a statement of the range of regimens agreed as acceptable for adjuvant chemotherapy and for first, second and third line palliative chemotherapy etc. Illustrative examples of treatment algorithms in different formats may be found in the appendix 1. There may be other formats which would be acceptable to the reviewers. Thus, a change of regimen or order of regimens may no longer comply with a previous treatment algorithm, but a change of one of the minor aspects of a treatment protocol would still comply.

Chemotherapy Treatment Algorithms

1

The NSSG, in consultation with the Network Chemotherapy Group (NCG) should agree a list of acceptable chemotherapy treatment algorithms. It should be updated bi-annually.

Notes:

- *The intention is **not** to require a single mandatory regimen for each clinical indication. It is to prevent individual practitioners having unorthodox, obsolete and unpredictably varying practice, which is against the opinion of their peers within the network.*
- *The NSSG should produce the algorithms for its compliance with this measure and the chemotherapy multi-professional team should produce a compatible list of algorithms for the NSSG's cancer site for their own service (measure 11-3S-122). The chemotherapy multi-professional team should agree lists with all the NSSGs relevant to their practice, for compliance with their measure.*
- *The network algorithm for a particular clinical situation may have a number of alternative regimens of which the multi-professional team need only agree those which it intends to use in its service. The multi-professional team need only address those clinical indications which are applicable to the scope of its practice. The key requirement is that all the algorithms on the multi-professional team list are compatible with the NSSG agreed list.*
- *This exercise should include oral chemotherapy.*
- *This measure is assessed as part of the responsibility of each NSSG, but from the NCG's point of view regarding the management of this process, the algorithms don't all need to be updated at the same time. It would seem sensible, however, to update all those for a given cancer site, at the same time.*

Compliance: The algorithms in place prior to the self assessment/peer review visit agreed by the Chair of the NSSG, and the Chair of the NCG.

For NSSGs meeting for three or more years since the publication of the measures, the algorithms are needed from the first year, then the agreed updates every two years up to

MEASURE DETAILS & DEMONSTRATION OF COMPLIANCE
the self assessment/peer review visit.

APPENDIX 1

1. Competencies for Nurses Undertaking Chemotherapy Administration

Introduction
Unless stated otherwise, the training competencies regarding an item on the list require knowledge of its theoretical aspects, and competency in the practical nursing aspects, of its prevention, recognition, management or maintenance, as relevant.

- Intravenous, oral and other routes of chemotherapy administration.
- Knowledge of the NHSE Intrathecal chemotherapy guidance.
- Holistic assessment of patients receiving chemotherapy.
- Peripheral and central venous access devices, including line complications.
- Mechanical pumps, scalp cooling devices and any other mechanical devices used in the chemotherapy service.
- Recognition of signs of myelosuppression; complications of myelosuppression.
- Common chemotherapy side effects including at least nausea, vomiting, stomatitis, diarrhoea, phlebitis and alopecia.
- Chemotherapy related oncological emergencies including extravasation, anaphylaxis and neutropenic sepsis.
- Health and safety aspects of chemotherapy administration, including protective clothing, safe handling and waste disposal.
- Knowledge of chemotherapy regimens used in the department - the information associated with a regimen is specified in the measures on the network and local lists of treatment algorithms and protocols.

2. Illustrative Examples of Treatment Algorithms.

NON-SMALL CELL LUNG CANCER (NSCLC)

Adjuvant Regime (Cisplatin/Vinorelbine)

Cisplatin	80mg/m^2	IV Infusion Day 1
Vinorelbine	30mg/m^2	IV Bolus Days 1 and 8

Repeat every 21 days x 4 cycles

Primary/ Palliative Chemotherapy (Stages III- IV)

For patients with advanced NSCLC, objective response rates to chemotherapy are about 20%, with responding patients achieving 6-12 month survival benefit. Patients should have a baseline CXR immediately prior to starting chemotherapy, and should be considered for treatment as part of relevant clinical trials

Stage IIIa
Patients with stage III NSCLC and good performance status (PS 0 & 1) should be offered appropriate trials. Off study, guidance recommends sequential chemo radiotherapy. Patients declining or not considered fit enough for chemotherapy where disease in encompassable in a radical radiotherapy field may be offered radiotherapy alone, in both cases using CHART when available.

Stage IIIb - IV
Chemotherapy for non-small cell lung cancer (NSCLC) should be offered to patients with good performance status (WHO 0,1) to improve survival, disease control and quality of life. NICE has recommended that: *Chemotherapy should be considered as an option for NSCLC patients unsuitable for curative treatment. Gemcitabine, Paclitaxel and Vinorelbine should be*

considered in 1st line treatment in combination with a platinum, Docetaxel should be considered in 2nd line' (2001).

Patients with poorer performance status (WHO 2, 3) may be suitable for consideration of treatment within the context of clinical trials e.g. TOPICAL.

In the palliative setting, typical practice would be to continue up to 4 cycles of treatment, with re-assessment every 2nd cycle.

Palliative Treatment regimens

Patients with performance status 0-1:
Consider combination therapy including a platinum.
Consider entry into BTOG2 (Gem/carbo vs Cis 50/gem vs Cis 80/gem)

Patients with performance status 2:
The median survival for this group of patients remains disappointing, although chemotherapy can still be considered for symptom control. When used, patients should be considered for entry into suitable trials e.g.: TOPICAL (erlotinib vs. placebo), or considered for carboplatin based combinations or vinorelbine monotherapy.

(NB. TOPICAL also open to PS 3)

Gemcitabine/Carboplatin

Gemcitabine	1200mgs/m^2	IV Infusion Days 1 and 8
Carboplatin	AUC 5	IV Infusion Day1

Repeat every 21 days

Carboplatin/Taxol

Paclitaxel	175mg/m^2	IV infusion Day 1
Carboplatin	AUC 6	IV infusion Day 1

Repeat every 21 days

Vinorelbine

Vinorelbine	30mg/m^2	IV bolus Days 1 and 8

Repeat every 3 weeks

Second Line chemotherapy

Second line therapy should only be considered in those with good performance status (0-1). Response Rates to chemotherapy are about 5-10%. Single agent Docetaxel is standard treatment. Patients with factors predictive of a response could be considered for Erlotinib (female, adenocarcinoma, Asian ethnic origin, never smokers) but this requires named patient approval from the PCT.

Docetaxel

Docetaxel	75mg/m^2	IV infusion Day 1

Repeat every 21 days up to a maximum of 4 cycles

Erlotinib

150mg daily continuous, review monthly

Non-chemotherapy trials

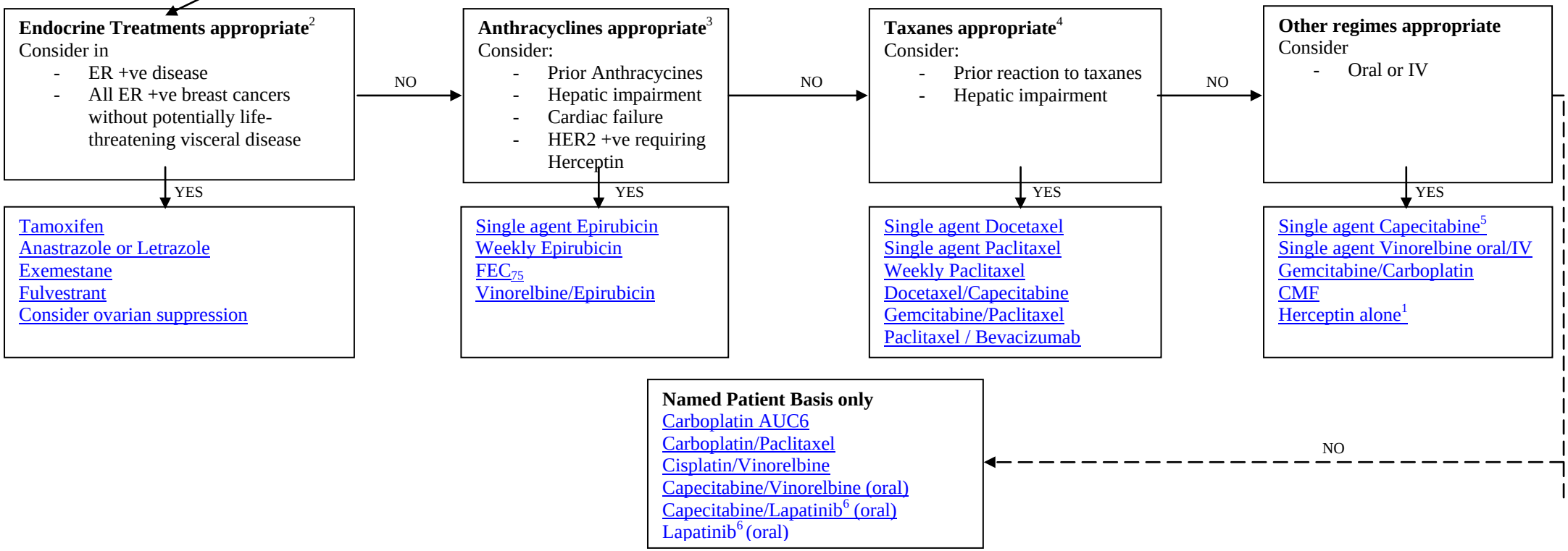
For all patients consider entry into:

LUN077- Fragmatic (Fragmin vs no fragmin)

LUN 066- ReSoLuCENT (Epidemiological study: lung cancer patients with either i) 1st degree relative with lung cancer aged <60 or ii) with 2 or more 1st or 2nd degree relatives with cancer at any age. Involves questionnaire and one blood test.)

Advanced Breast Protocol

In all cases consider **Zoledronic acid** for bone metastases and **Herceptin** for HER2 +ve disease[1]



5

1 Herceptin

- Initiated as single agent or alongside endocrine treatment or chemotherapy regimes (not anthracyclines).
- Consider herceptin beyond progression for cerebral metastases.
- Consider lapatinib (capecitabine) after disease progression on herceptin (ICDF see below)

2 Endocrine Treatment

- ER weakly or strongly +ve
- Consider in poor performance status, elderly or minimal symptomatic disease.
- Consider ovarian suppression in pre-menopausal women

Regimes

- Tamoxifen
    - Caution with previous thromboembolic disease

- Aromatase inhibitor – Anastrazole, Letrozole, Exemestane
    - Post-menopausal
    - Pre-menopausal with ovarian suppression (surgical or goserelin)

- Fulvestrant
    - Treat 2 weekly for 2 cycles then 4 weekly thereafter.
    - 250mg preparation used.

3 Anthracyclines

- Cumulative maximum tolerated dose epirubicin 750mg/m^2.
- Also consider prior use of other Anthracyclines (e.g. adjuvant TAC)
- Significant increase in cardiac toxicity used concurrently with herceptin.

Regimes

- Single agent Epirubicin 90mg/m^2
- Weekly Epirubicin 25mg/m^2 for hepatic impairment / poor performance status
- FEC75 good performance status good prognosis disease only
- Epirubicin 35mg/m^2 and Vinorelbine

4 Taxanes

- Caution with prior reaction to Taxanes

Regimes

- Docetaxel
- Paclitaxel
- Capecitabine/Paclitaxel
- Weekly Paclitaxel for hepatic impairment / poor performance status
- Gemcitabine/Paclitaxel
- Carboplatin/paclitaxel (named patient basis only)
- Bevacizumab/docetaxel (ICDF see below)

5 Capecitabine

- Single agent capecitabine 1g/m^2 bd may be continued until progression

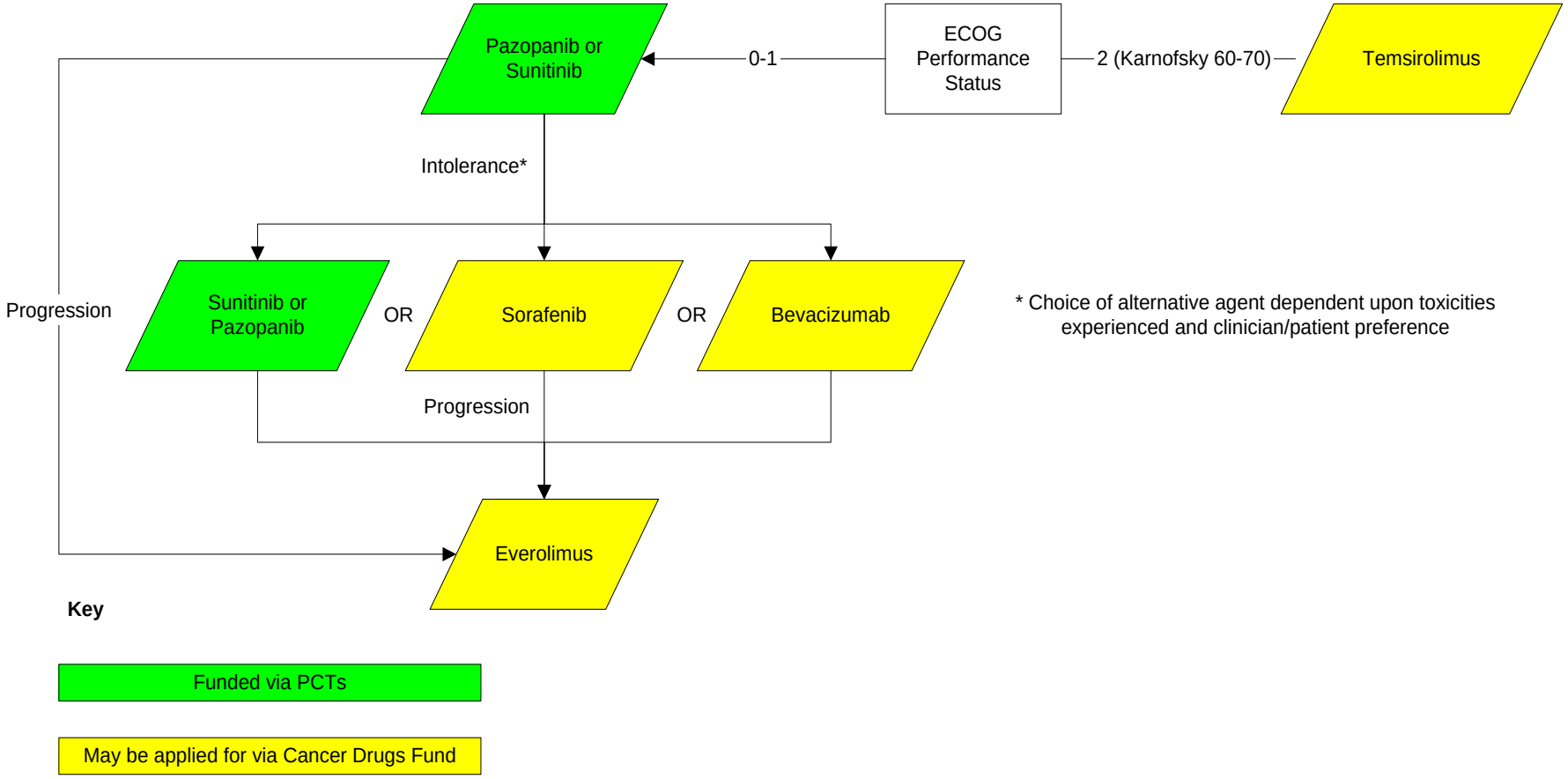
6 ICDF

The following have been approved for use on a case by case basis through NHS

Yorkshire and the Humber Interim Cancer Drug Fund (ICDF).

- Bevacizumab with a taxane 1st line treatment of triple negative metastatic breast cancer
- Lapatanib with Capecitabine has been approved for HER2 +ve advanced or metastatic breast cancer with progression following prior therapy that has included anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting.

Treatment Algorithm for Metastatic Renal Cell Carcinoma



Wherever possible, eligible patients should be offered access to treatment as part of clinical trials

Updated national guidance in safe administration of intrathecal chemotherapy: Waiver on dilutions for UKCCSG Centres

Having read the updated "National Guidance on the Safe Administration in Intrathecal Chemotherapy", we the undersigned have decided that at ..... NHS Trust, a UKCCSG Centre, intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) can be given to children of any age at concentrations higher than those specified at para 78 of the guidance.

We confirm that a risk assessment was carried out before reaching this decision and that this practice is:

- Addressed in the local policy; and
- Covered in induction and training programmes.

We confirm that patient safety will not be adversely affected by the decision.

Signature

Chief Executive _____

Date: / /

Medical Director (on behalf of Clinical Directors) _____

Date: / /

Director of Nursing _____

Date: / /

Chief Pharmacist _____

Date: / /

Note: This waiver expires 12 months from the date it is signed

APPENDIX 2

2.1 Role of Network (Tumour) Site Specific Groups (NSSGs)

Membership

Network tumour site-specific groups should be multidisciplinary; with representation from professionals across the care pathway; involve users in their planning and review; and have the active engagement of all MDT leads from the relevant constituent organisations in the network.

Service Planning

NSSGs should ensure that service planning:

- is in line with national guidance/standards (including reconfiguration where necessary);
- covers the whole care pathway;
- promotes high quality care and reduces inequalities in service delivery;
- takes account of the views of patients and carers;
- takes account of opportunities for service and workforce redesign;
- establishes common guidelines, including clear referral guidelines.

NSSGs should:

- recommend priorities for service development to the network board. (In some networks this is via an advisory clinical group, consisting of membership from chairs of network groups, trust lead clinicians and the network team);
- ensure decisions become integrated into constituent organisational structures and processes.

Service Improvement/Redesign

- all NSSGs and individual cancer teams should commit to service improvements;
- process mapping and capacity and demand analyses should become part of the norm;
- requests for additional resources from NSSGs should be accompanied by evidence of involvement in service improvement/redesign;
- NSSGs should develop/approve high quality information for patient, for use across the network.

Service Quality Monitoring and Evaluation

NSSGs should:

- agree on priorities for common data collection (in line with national priorities e.g. for waiting times, registries and NCASP), but go beyond this where possible;
- review the quality and completeness of data, recommending corrective action where necessary;
- produce audit data and participate in open review;
- ensure services are evaluated by patients and carers;
- monitor progress on meeting national cancer measures and ensure action plans agreed following peer review are implemented;
- report identified risks/untoward incidents to ensure learning is spread.

Workforce Development

NSSGs should:

- consider the overall workforce requirements for the NSSG;
- consider the education and training needs of teams and, where appropriate, of individuals;
- liaise with the network board and with the workforce development confederation to ensure that appropriate workforce numbers and CPD are available;
- promote links between teams through rotation of staff;
- develop common recruitment/retention strategies;
- take account of opportunities for skill mix changes.

Research and Development

- NSSGs should agree a common approach to research and development, working with the network research team, participating in nationally recognised studies whenever possible.

Annual Work Plan and Report

NSSGs should:

- draw the above together in an annual work plan in the context of a prioritised clinical governance development plan, for approval by the network board;
- ensure this is fed into commissioning, with agreements specifying standards, service developments and improvement, data collection, audit, research, education and training;
- provide an annual report of activity to feed health economy clinical governance reporting processes.

2.2 The Responsibilities of MDT members

Responsibilities of the MDT lead clinician

- ensure that objectives of MDT working (as laid out in Manual of Cancer Services) are met:
    - to ensure that designated specialists work effectively together in teams such that decisions regarding all aspects of diagnosis, treatment and care of individual patients and decisions regarding the team's operational policies are multidisciplinary decisions;
    - to ensure that care is given according to recognised guidelines (including guidelines for onward referrals) with appropriate information being collected to inform clinical decision making and to support clinical governance/audit;
    - to ensure mechanisms are in place to support entry of eligible patients into clinical trials, subject to patients giving fully informed consent;
- overall responsibility for ensuring that MDT meeting and team meet peer review quality measures;
- ensure attendance levels of core members are maintained, in line with quality measures;
- ensure that target of 100% of cancer patients discussed at the MDT is met;
- provide link to NSSG either by attendance at meetings or by nominating another MDT member to attend;
- lead on or nominate lead for service improvement;
- organise and chair annual meeting examining functioning of team and reviewing operational policies and collate any activities that are required to ensure optimal functioning of the team (e.g. training for team members);
- ensure MDT's activities are audited and results documented;
- ensure that the outcomes of the meeting are clearly recorded and clinically validated and that appropriate data collection is supported;
- ensure target of communicating MDT outcomes to primary care is met.

Responsibilities of the MDT Co-ordinator

- facilitate and co-ordinate the functions of the multidisciplinary team meetings;
- ensure the appropriate proportions of patients are discussed at MDTs;
- help with the introduction and changes to proformas used to ensure all patients are discussed, treated appropriately and outcomes are recorded and reviewed. Ensuring patients' diagnoses,
- investigations, and management and treatment plans are completed and added to the patient's notes;
- managing systems that inform GP's of patient's diagnosis, decisions made at outpatient appointment etc;
- working with staff to ensure all patients have a booked first appointment, investigation and procedure and record details of patients coming via a different route;
- working with key MDT members to identify areas where targets are not achieved, undertake process mapping to identify bottlenecks;
- undertake demand and capacity studies where appropriate;
- report changes to MDTs on a monthly basis;
- data collection and recording of data;
- to manage the systems according to guidelines, monitoring milestones and submitting the required reports in the given format and required times;
- keep comprehensive diary of all team meetings;
- record attendance at meetings;
- take minutes at the multidisciplinary meetings, type notes back in the required format and distribute to all concerned;
- the post holder will be expected to be instrumental in the development of databases to capture patient information and report this to the clinicians on a weekly basis;
- inform lead cancer manager of waiting times for patients when these exceed appropriate targets;
- ensure lists of patients to be discussed at meetings are prepared and distributes in advance;
- ensure all correspondence, notes, x-rays, results, etc are available for the meetings;
- ensure action plans for patient care are produced with agreed reviews;
- assist in capturing cancer data on all patients and assist in the development of systems to complement the cancer audit system;
- ensure members or their deputy are advised of meetings and any changes of date, venue, etc.