Facilities for the treatment of adults with haematological malignancies – ‘Levels of Care’: BCSH Haemato-Oncology Task Force 2009


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Introduction
The British Committee for Standards in Haematology (BCSH) Clinical Haematology Task Force last produced guidelines on levels of care relating to the provision of facilities for patients with haematological malignancies and severe bone marrow failure in 1995.¹ Since then, the range of diagnostic methods for haematological malignancies has broadened, whilst the complexity and toxicity of many of the treatments for these diseases has increased considerably. Furthermore, there have been numerous important national developments in the provision of care for patients with cancer in general and for those with haematological malignancies in particular. These developments include:

- National Institute for Clinical Excellence. Guidance on Cancer Services Improving Supportive and Palliative Care for Adults with Cancer – The
The levels of care

As before, the approach has been to define levels of care which reflect the facilities and resources required to treat patients with haematological malignancies according to:

- the complexity of the treatment delivered;
- the duration of anticipated neutropenia following chemotherapy;
- in some instances the rarity of the disease subtype.

Three major levels of care are proposed, with Level 2 being subdivided into Levels 2a and 2b:

- Level 1;
- Level 2a;
- Level 2b;
- Level 3.

Although these levels of care are described as distinct entities, provision of care should be flexible so that any patient can have access to appropriate components of the services across different levels when necessary. As they are described, these levels of care relate predominantly to the facilities required for the delivery of chemotherapy for haematological malignancies. The section on the arrangements for emergency care of patients with chemotherapy-related complications addresses the provision of this important aspect of care for patients with chemotherapy-related complications (e.g. neutropenic sepsis) presenting to other units.

The criteria against which these levels of care are assessed and the resources required to meet them are outlined in Table 1.

Intensity and duration of treatment regimen

The nature of the recommended treatment regimen will determine the depth and extent of marrow suppression, the complexity of other side-effects, and the resources required to deliver it. Thus:

- Level 1 treatment would not normally be expected to result in significant neutropenia, although this might occur for a brief period (less than 7 days). Such treatment can be given on an out-patient basis, either orally or intravenously. Examples of this level of treatment include oral hydroxyurea, melphalan.
- Level 2a treatment more predictably results in short periods of bone marrow suppression, with neutropenia of usually less than 7 days duration. Examples include: cyclophosphamide, hydroxydaunorubicin, vincristine, prednisolone (CHOP), doxorubicin, bleomycin, vinblastine, dacarbazine.

The measures defined in these initiatives provide for a detailed specification of the standards that need to be met with respect to the care of patients with haematological cancers and for their external peer review assessment.

In view of the developments in this area of clinical work, the BCSH felt it appropriate to review its document of 1995 so as to provide an updated guideline for use both by providers of this clinical care and by those who commission it. The proposal to revisit this was considered at a session at the BSH meeting in Bournemouth in 2007, and a consensus agreement obtained. Subsequently, a survey questionnaire was conducted of all haematologists in the UK and the results presented at the BSH meeting in Glasgow in 2008. The following guidelines take into account the results of the survey questionnaire in addition to the work of the members of the BCSH Haematology-Oncology Task Force and comments from patient support groups. This document does not address the facilities relating to stem cell transplantation, which are themselves subject to accreditation standards published by JACIE (Joint Accreditation Committee of International Society for Cellular Therapy and European Bone Marrow Transplant).

It is recognised that in some centres the care of patients with lymphoma is undertaken by oncologists.
<table>
<thead>
<tr>
<th>Disease management</th>
<th>Level 1</th>
<th>Level 2a</th>
<th>Level 2b</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complexity of management</td>
<td>Low</td>
<td>Moderate</td>
<td>High</td>
<td>Complex regimens includes curative intent ALL</td>
</tr>
<tr>
<td>Regimen delivery</td>
<td>Out-patient but minimal intravenous combination/ infusion (unless antibody therapy)</td>
<td>Day case chemotherapy but no in-patient chemotherapy</td>
<td>In-patient</td>
<td>In-patient, complex</td>
</tr>
<tr>
<td>Regimen related neutropenia/ immunosuppression</td>
<td>Not expected</td>
<td>Short, &lt;7 days</td>
<td>Prolonged neutropenia and/or profound immunosuppression</td>
<td>Prolonged neutropenia and/or profound immunosuppression</td>
</tr>
<tr>
<td>Risk of serious complications</td>
<td>Minimal</td>
<td>Low</td>
<td>Significant</td>
<td>Significant</td>
</tr>
<tr>
<td>Examples of regimens</td>
<td>Melphalan, hydroxycarbamide</td>
<td>CHOP, ABVD, R-CVP, FCR, bortezomib therapies, treatment of AML with palliative intent</td>
<td>Treatment of AML with curative intent, DHAP, IVE</td>
<td>Treatment of ALL with curative effect</td>
</tr>
<tr>
<td>Staffing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>Consultant haematologist has sessions in Level 2 or higher; 24 h telephone access to consultant haematologist</td>
<td>24 h cover from consultant haematologist and medical junior staff. Cross-cover of in-patient beds acceptable between sites</td>
<td>24 h cover by attending consultant haematologist. On-site designated junior trainee or sub-consultant non-career grade during weekdays.</td>
<td>24 h cover by attending consultant haematologist. 24 h specialist middle grade cover (not necessarily on-site). On-site designated haematology junior trainees during weekdays.</td>
</tr>
<tr>
<td>Nursing</td>
<td>Dedicated nurse with sessions in Level 2 or higher; access to specialist haematology/oncology trained nurse (see text for details)</td>
<td>On-site specialist haematology/oncology trained nurse (see text for details) weekdays</td>
<td>On-site 24 h cover with specialist haematology/oncology trained nurse (see text for details); ability to immediately increase ratio 1:2 patients as required</td>
<td>On-site 24 h cover with specialist haematology/oncology trained nurse (see text for details); ability to immediately increase ratio 1:2 patients as required</td>
</tr>
<tr>
<td>Support specialists/facilities</td>
<td>Out-patient care</td>
<td>Access to day care unit with facilities for blood component transfusions</td>
<td>Haematology day unit, providing facilities for isolation, long duration intravenous infusions, blood component transfusions</td>
<td>Haematology day unit, providing facilities for isolation, long duration intravenous infusions, blood component transfusions</td>
</tr>
<tr>
<td></td>
<td>In-patient beds</td>
<td>Access to beds in facility</td>
<td>Specific beds on site on one dedicated ward; access to single rooms with en-suite facilities</td>
<td>Isolation facilities (en-suite) in ward designated for haematology patients; ability to administer overnight chemotherapy infusions</td>
</tr>
<tr>
<td></td>
<td>Direct access to dedicated beds out of hours</td>
<td>Agreed access to emergency unit with agreed protocols for management of complications of chemotherapy</td>
<td>Admission to emergency unit with agreed protocols for management of complications of chemotherapy</td>
<td>Dedicated access to dedicated ward</td>
</tr>
<tr>
<td></td>
<td>Pharmacist</td>
<td>Access to specialist pharmacist</td>
<td>Access to specialist pharmacist</td>
<td>Dedicated haematology pharmacist</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2a</th>
<th>Level 2b</th>
<th>Level 3</th>
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</thead>
<tbody>
<tr>
<td>Support specialists/facilities</td>
<td>Consultant clinical oncologists available for consultation; access to radiotherapy facilities</td>
<td>Consultant clinical oncologists available for consultation; access to radiotherapy facilities</td>
<td>Designated consultant clinical oncologists input; access to radiotherapy facilities</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td></td>
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<tr>
<td>Tunnelled central line insertion facilities and personnel</td>
<td></td>
<td></td>
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<tr>
<td>Intrathecal administration (administered according to DH Intrathecal Policy)</td>
<td></td>
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<tr>
<td>High Dependency Unit</td>
<td>Access</td>
<td></td>
<td>On-site</td>
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<tr>
<td>Intensive Therapy Unit</td>
<td>Access</td>
<td></td>
<td>On-site</td>
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<tr>
<td>Dialysis/haemofiltration</td>
<td>Access</td>
<td></td>
<td>On-site</td>
</tr>
<tr>
<td>Microbiology</td>
<td>Access</td>
<td></td>
<td>Designated consultant microbiology input</td>
</tr>
<tr>
<td>Radiology</td>
<td></td>
<td></td>
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<tr>
<td>Computerised tomography/magnetic resonance imaging</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PET</td>
<td>Access</td>
<td></td>
<td>On-site 24 h</td>
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<tr>
<td>Interventional radiology</td>
<td>Access</td>
<td></td>
<td>On-site</td>
</tr>
<tr>
<td>Bronchoscopy/respiratory</td>
<td>Access</td>
<td></td>
<td>On-site</td>
</tr>
<tr>
<td>Access to leucopheresis</td>
<td>Refer patient to Level 2 or above</td>
<td>Access to but ideally on site</td>
<td>Access</td>
</tr>
<tr>
<td>Histopathology</td>
<td>Access</td>
<td></td>
<td>Access</td>
</tr>
<tr>
<td>Patient-centred care: fertility, psychological, specialist and general palliative care, social support, complementary therapy, spiritual, carer support and bereavement</td>
<td>Meeting IOG and MDT standards</td>
<td>Meeting IOG and MDT standards</td>
<td>Meeting IOG and MDT standards</td>
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<tr>
<td>MDT</td>
<td>Meeting IOG and DH standards</td>
<td>Meeting IOG and DH standards</td>
<td>Meeting IOG and DH standards</td>
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<tr>
<td>Trial entry</td>
<td>Research nurse support</td>
<td>Access</td>
<td>Access</td>
</tr>
</tbody>
</table>

ABVD: doxorubicin, bleomycin, vinblastine, dacarbazine; AML: acute myeloid leukaemia; ALL: acute lymphoblastic leukaemia; CHOP: cyclophosphamide, hydroxydaunorubicin, vincristine, prednisolone; DH: Department of Health; DHAP: dexamethasone, high dose cytarabine, cisplatinum; FCR: fludarabine, cyclophosphamide, rituximab; IOG: improving outcomes guidance; IVE: ifosfamide, etoposide (VP16) epirubicin; MDT: Multi-Disciplinary Team; PET: positron emission tomography; R-CVP: rituximab, cyclophosphamide, vincristine, prednisolone.
(ABVD), rituximab containing combinations [flu-
darabine, cyclophosphamide, rituximab (FCR),
rituximab, cyclophosphamide, vincristine, prednis-
olone (R-CVP), rituximab cyclophosphamide,
hydroxydaunorubicin, vincristine, prednisolone
(R-CHOP), etc.], bortezomib therapies and non-
intensive treatment for acute myeloid leukaemia
(AML).

- Level 2b treatment encompasses those that will
predictably cause prolonged periods of neutrope-
nia, would normally be given on an in-patient
basis, and which may need to be given at weekends
as well as during the week. These regimens are
more complex to administer than at Level 1 or 2a
(for example, in terms of drug scheduling) and
have a greater likelihood of resulting in medical
complications in addition to predictable prolonged
neutropenia. Consequently, the resources required
to deliver these more complex regimens are greater
than at Level 1 or 2a. Such regimens include those
used to treat AML with curative intent, and
salvage chemotherapy regimens for relapsed
aggressive histology lymphomas [for example,
dexamethasone, high dose cytarabine, cisplatinum
(DHAP) and ifosfamide, etoposide (VP16) epir-
ubicin (IVE)]. It is acknowledged that with some of
these regimens the patient will be at home during
the period of neutropenia. As with patients treated
at Levels 1 and 2a, clear arrangements for the
management of chemotherapy-related emergencies
should be in place.

- Level 3 treatment refers to those regimens that are
complex, and, as with Level 2b, may have a high
incidence of complications. In addition these
treatments are designed for rare haematological
malignancies where centralisation of care at
regional centres is considered to be advantageous,
for example in terms of the familiarity of the
biology of the rare diseases and the treatment
protocols used. An example of this is the modern
in-patient management phase of acute lympho-
blastic leukaemia.

**Staffing**

The staffing requirements at these different levels
reflect the complexity of the treatment regimens and
the attendant likelihood of complications. In line
with national guidance, there should, at all levels, be
formally agreed criteria with pharmacy to identify
those medical staff who may initiate chemotherapy
and those who may prescribe repeated courses.²

Level 1: The consultant haematologist at a Level 1
unit would have sessions there but would also have
sessions at a Level 2 unit or above. Whilst not on-site
at all times, there should nevertheless be 24 h
telephone access for consultant advice if needed.
Similarly, there should be dedicated specialist nurse
sessions at the Level 1 unit with professional links
with Level 2 or above.

Level 2a: Consultant haematologist with junior
medical staff cover should be provided on a 24 h/
7 day a week basis. Cross-cover of in-patient beds
between different sites at consultant level would be
satisfactory and there should be specialist haematol-
ogy nursing provision during the working week.

Level 2b: 24 h cover by an attending haematologist
would be expected whilst designated junior trainee
or sub-consultant non-career grade staff would be
provided during the working week. On-site specialist
haematology nursing would be provided during the
week, and there should be provision for 24 h cover
with haematology oncology trained nurses. There should
be the resource to increase the number of nurses to
achieve a nurse/patient ratio of 1:2 if required, for
example in the setting of a patient requiring high
dependency nursing.

Level 3: As at Level 2b, there should be 24 h cover
by an attending consultant haematologist. There
should also be 24 h specialist middle grade medical
staff cover during the weekdays/weekends. With
respect to nursing, there would need to be on-site
specialist haematology nurse cover during the week
with 24 h cover with haematology oncology trained
nurses. As at Level 2b, there should be the resource
to immediately increase the number of nurses to
achieve a nurse/patient ratio of 1:2.

**Specialist nurse training**

Suitable nursing training would constitute 1 year or
more in the specialty with a higher appropriate
qualification, for example, a CAT level III or
equivalent in Clinical Haematology or Haemato-
oncology including a specialist module accredited to
20 credits at the first degree or equivalent in either of
these two nursing specialties. A nurse who already
holds other training qualifications which are of equal
or greater academic professional standing should be
considered compliant. This includes qualifications
which predate the credits system for example ENB
237 or A27.³ For the purposes of chemotherapy
administration alone, Trusts may agree with their
network the levels of internal training required to
deliver this aspect of the service.³ This would include

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³ "Handbook of Haematology" 2010
Support facilities
The facilities required to support the different levels of care for haematological malignancies reflect the complexity of the treatments and the likelihood of complications that may arise from them. These facilities include access to out-patient care, in-patient beds (whether dedicated or otherwise), pharmacy support, diagnostics services (radiology, microbiology and other pathology services), and those facilities necessary to support seriously ill patients [high dependency unit (HDU), intensive care unit (ICU), haemodialysis or haemofiltration, bronchoscopy, leucapheresis]. The need for these support service to be on-site would vary, whilst it is accepted that some may be off-site at all levels (e.g. histopathology). In all cases, however, the provision of these services would need to comply with the Improving Outcome Guidance, be in line with the acceptable practice of the Multi-Disciplinary Team operating procedures and, if intrathecal chemotherapy is administered, with the Department of Health Intrathecal Policy.4

At all levels, entry of patients into clinical trials should be encouraged, with support from a research nurse (or equivalent) being available to facilitate this. Ideally, there should be a research nurse on site at Levels 2b and 3, although access to one off site would be appropriate at Levels 1 and 2a.

Level 1: There would need to be access to a day care unit with appropriate facilities for blood product transfusion. In the event of a patient needing admission then there should be agreed protocols for the management of the common complications of chemotherapy (e.g. neutropenic sepsis) which are understood and readily accessible in the emergency department and admitting medical units. Patients should be admitted to beds within the general medical pool with appropriate junior doctor cover (see above). There should be access to the other support services (see spreadsheet), with standard radiological services available on site during working hours, and whilst access to cross-sectional and radio-isotope techniques [computerised tomography scanning (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET)] should be available, this may be off-site.

Level 2a: The day care facilities should include the provision of facilities for intravenous infusions of long duration, whilst in-patient beds should be available on a ward designated for haematology with access to single rooms which have en-suite facilities. As at Level 1, it is important that the management of chemotherapy complications is subject to agreed protocol so that all those concerned, especially in the emergency department and admitting medical units, are clear as to the appropriate management. There should be access to a specialist pharmacist and there should be an HDU on site with ready access to an ICU. Provision for CT and MRI should ideally be on site, as would provision for interventional radiology. Other support facilities should be readily accessible, but not necessarily on site (e.g. PET scanning, indwelling tunnelled central venous catheters, dialysis, leucapheresis).

Level 2b: In addition to the requirements of Level 2a, there should be the provision for direct access to a dedicated haematology ward with isolation and en-suite facilities and a dedicated haematology/oncology pharmacist. Support of acutely sick patients should be on-site (HDU, ICU, central line insertion facilities, dialysis or haemofiltration, interventional radiology, bronchoscopy) and there should be access to one or more clinical oncologists who are designated for this group of patients and who can be contacted for advice on radiotherapy.

Level 3: In addition to Level 2b, it would be anticipated that a Level 3 unit would have designated consultant microbiology input (in contrast to the other levels, which require access to the microbiology service and advice), and the ability to perform leucapheresis on site.

In addition to the above, for all levels there is a need to have provision for other, patient-centred, services. Included in this are those issues around fertility counselling and gamete preservation. In line with the National Institute for Clinical Excellence Guidance on Cancer Services Improving Supportive and Palliative Care for Adults with Cancer,5 there should be access to appropriate palliative care services, psychological and social support as well as to appropriate bereavement care for the patients’ families and carers. There should also be access to suitable spiritual support for the patients and their carers. Information about complimentary services should be obtainable if requested and any provision for complimentary therapy should comply with the Department of Health guidelines.6

Arrangements for emergency care of patients with chemotherapy-related complications
An important consideration in reviewing and updating the recommendations of the levels of care is the
recognition that patients who have received chemotherapy in one unit may present with complications of the treatment to a different unit. This is particularly the case where there are long times involved in travelling to and from the cancer centre, for example greater than 2 h or a round trip of 4 h. In these circumstances, agreement will need to be reached on the arrangements for acute in-patient care should the patient present as an emergency with chemotherapy-related complications to their local hospital rather than treating hospital.

The principles of care of patients in these circumstances have recently been outlined in the report from the National Chemotherapy Advisory Group (2008)\(^7\) and the report of National Confidential Enquiry into Patient Outcome and Death: ‘For better, for worse?’(2008).\(^8\) In summary:

- Centres that deliver chemotherapy should agree arrangements, coordinated at network level, for the management of their patients with the emergency departments, medical units, and haematology departments where they might present.
- These arrangements must include protocols covering the management of common complications (e.g. neutropenic sepsis) as well as transfer arrangements as necessary.
- Appropriate training of the medical and nursing staff in these settings is essential and training programs should incorporate the necessary modules to cover these educational requirements.
- Good communication, both verbal and written, between the centre and surrounding emergency and medical units is essential. Expert assessment must be readily sought and be available, whilst written information about the patients should be accessible as necessary.

In addition, there would need to be arrangements between the different haematology units functioning at different levels:

- Levels 1 and 2a haematology units would need to have close links with Level 2b units (see above for descriptions of the levels) to ensure prompt and seamless care of their patients in the event of unexpected or prolonged complications arising following the out-patient based administration of chemotherapy. This includes the scenario where both units are in the same Trust, the Level 1 or 2a unit being a ‘satellite’ unit of the main unit, designated as Level 2b or 3.
- In particular, there would need to be explicit agreed criteria and arrangements for the transfer of patients from Levels 1 and 2a units to Level 2b units.

References


