Title:	**Echelon classification**	
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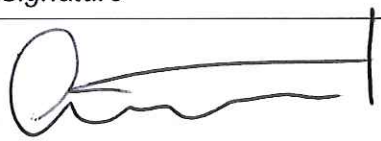
Author name	*Signature*	*Date*
P. Huijgens		29 07 2013
P. Westveer		29-July-2013
Approver name	*Signature*	*Date*
PSonneveld		29/07/2013

The purpose of the echelon classification is to determine up-front which sites are able to participate in specific HOVON trials, as is described in the HOVON policy “site selection”.

The echelon classification is limited to sites from the Netherlands.

For allogeneic and autologous stem cell transplantations there is a system of permits originated via the Dutch Ministry of Health, Welfare and Sport, based on criteria from the Health Council ('Haematopoietic stem cells'; Health Council, 10-09-2003). These criteria, some of them modified, can be used to define four 'intensive care' echelons. In addition there are hospitals fully capable of participating in non-intensive care trials.

The following echelons are recognized:

Level A:

Hospitals holding a permit for allogeneic and autologous stem cell transplantations, providing both hematological intensive care (acute leukemia etc) and non-intensive hematological care. In general, these sites are able to participate in all HOVON trials.

Level B:

Hospitals with a permit for autologous (but not allogeneic) stem cell transplantation, providing both hematological intensive care (acute leukemia etc) and non-intensive hematological care. In general, these sites are able to participate in all HOVON trials, with the exception of AlloSCT trials.

Level C-HIC:

Hospitals providing hematological intensive care (acute leukemia etc) as well as non-intensive hematological care. In general, these sites are able to participate in all HOVON trials including acute leukemia trials. They may participate in trials requiring Allo or AutoSCT as part of the protocol schedule provided that they have made an arrangement to refer trial patients to a Level A or Level B site for Allo or AutoSCT including follow up care.

Level C-SCT:

Hospitals providing care after autologous stem cell transplant as well as non-intensive hematological care. In general, these sites are able to participate in HOVON trials with a protocol schedule involving non-intensive hematological care that does not cause long-term and/or deep pancytopenia. They may participate in trials requiring Allo or AutoSCT as part of the protocol schedule provided that they have made an arrangement to refer trial patients to a Level A or Level B site for Allo or AutoSCT. Trial patients may return to this site for follow up immediately after the AutoSCT procedure.

Level D:

Hospitals providing non-intensive hematological care without long-term and/or deep pancytopenia. In general, these sites are able to participate in HOVON trials with a protocol schedule involving non-intensive hematological care that does not cause long-term and/or deep pancytopenia. They may participate in trials requiring Allo or AutoSCT as part of the protocol schedule provided that they have made an arrangement to refer trial patients to a Level A or Level B site for Allo or AutoSCT including follow up care.

It is possible that a single site classifies for both the C-SCT and C-HIC echelon.

The criteria for each level are outlined in Table 1.

The echelon criteria will be reviewed by the HDC monitors during Site Evaluation Visits.

The monitors will report to the HOVON board that will use this information to determine the correct echelon classification of the site.

Table 1: Echelon classification criteria

Criteria	Level A	Level B	Level C-HIC	Level C-SCT	Level D
Physicians					
The hematologists and oncologists involved in the care of hematological trial patients operate as a single team and perform hospital rounds together. They coordinate their schedules to ensure uninterrupted availability of care for trial patients (e.g. absence due to vacations or conferences)	●	●	●	●	●
At least 1.8 fte employed, divided over at least 0.8 fte hematologists and at least 1 other physician who is either hematologist or oncologist.					●
An internist with affinity for hematological or oncological care can be called on directly by nursing staff 24 hours a day, seven days a week.					●
At least 3.5 fte employed, divided over at least 1.5 fte hematologists and at least 2 other physicians who are either hematologist or oncologist.	●	●	●	●	
The hematologists and oncologists perform hospital rounds during the weekend.	●	●	●	●	
A hematologist or oncologist can be called on directly by nursing staff 24 hours a day, seven days a week.	●	●	●	●	

Criteria	Level A	Level B	Level C-HIC	Level C-SCT	Level D
Nurses					
Nurses involved in the care of trial patients are familiar with the trial protocol and nursing guidelines.	●	●	●	●	●
Continuous specialist nursing care is available in day treatment. The nurses are familiar with the type of treatments that are used in the trials. They are able to recognize and respond to known complications of chemotherapy, and follow the trial specific nursing guidelines.	●	●	●	●	●
At least 30% of the nurses have completed a specialized training in hematological care at an accredited institution.	●	●	●	●	
Medical care organization					
Access to radiotherapy facilities.	●	●	●	●	●
Collaboration with level A or level B hospital with direct access to their hematologists for consultation.			●	●	●
JACIE accreditation for Allogeneic stem cell transplants	●				
JACIE accreditation for Autologous stem cell transplants	●	●			
Cooperation agreement with level A or level B hospital to ensure post-transplant care in accordance with JACIE standards. The agreement has been reviewed and accepted as part of the JACIE accreditation of the level A or level B hospital.				●	
Availability of transfusion care 24 hours a day, seven days a week.	●	●	●	●	
Availability of an Intensive Care unit.	●	●	●	●	
Agreements on transmural care pathways.	●	●	●	●	

Criteria	Level A	Level B	Level C-HIC	Level C-SCT	Level D
Adequate facilities for immune-incompetent patients: separated rooms or ward, active infection prevention protocol with involvement of a hospital hygiene specialist.	●	●	●	●	
Availability of in-house consultants for neurology and pulmonology.	●	●	●	●	
Intensive in-house support of medical-microbiologists with experience in problems caused by disrupted immune response: weekly consultations with the physicians, able to perform weekly cultures for infection surveillance with results available within 72 hours.	●	●	●	●	
Multidisciplinary meetings between physicians and persons responsible for the execution and interpretation of diagnostic tests.	●	●	●	●	
Continuous presence of pancytopenic patients in the department.	●	●	●	●	
At least 10 patients with acute leukemia per year.	●	●	●		
Diagnostic facilities					
Availability of in-house CKL accredited facilities for hematology and blood chemistry with the ability to provide test results within 24 hours.	●	●	●	●	●
Access to facilities for cytogenetics and FISH, participating in review rounds (at least 80% of samples reviewed) and with the ability to provide test results within 72 hours.	●	●	●	●	●
Access to facilities for pathology, participating in review rounds (at least 80% of samples reviewed) and with the ability to provide test results within 72 hours.	●	●	●	●	●
Availability of in-house imaging facilities (x-ray and CT) for surveillance of infections and complications with the ability to provide imaging results and interpretation of those results within 24 hours.	●	●	●	●	●

Criteria	Level A	Level B	Level C-HIC	Level C-SCT	Level D
Access to imaging facilities (x-ray, CT and PET) participating in review rounds (at least 80% of diagnostic images reviewed) and with the ability to provide imaging results and interpretation and/or measurements of those results within 72 hours.	●	●	●	●	●
Access to facilities for bacteriology, virology, mycology and parasitology.	●	●	●	●	
Availability of in-house CKL accredited facilities for bone marrow morphology with the ability to provide test results within 24 hours.	●	●	●		
Access to facilities for immuno phenotyping, participating in review rounds (at least 80% of samples reviewed) and with the ability to provide test results within 72 hours.	●	●	●		
Access to facilities for molecular diagnostics participating in ModHem quality rounds and with the ability to provide test results within 72 hours.	●	●	●		
Pharmacy					
In-house KNMP registered hospital pharmacist available.	●	●	●	●	●
Pharmacy staff is aware of GCP requirements regarding study drug handling and drug accountability.	●	●	●	●	●
Pharmacy has facilities to adequately store study drug: no unauthorized access, separate from regular medication, refrigerated with temperature log if necessary.	●	●	●	●	●
Pharmacy has facilities to handle hazardous substances (cytostatic drugs)	●	●	●	●	●
Pharmacy has (access to) facilities to prepare aseptic intravenous medication.	●	●	●	●	●
Access to facilities for pharmacological assays (drug blood levels)	●	●	●	●	
Availability of pharmacy 24 hours a day, seven days a week for preparation and dispensing of medication.	●	●	●		

Criteria	Level A	Level B	Level C-HIC	Level C-SCT	Level D
Investigator qualifications					
The hematologist(s) who will act as local investigator for trials has prior experience in clinical trials.	●	●	●	●	●
The hematologist(s) who will act as local investigator for trials is aware of and willing and able to fulfill all investigator responsibilities.	●	●	●	●	●
The hematologists and oncologists who will act as (sub-)investigator for trials have completed a GCP training course.	●	●	●	●	●
Trial support staff					
All trial support staff is trained in their delegated trial tasks.	●	●	●	●	●
All trial support staff has completed a GCP training course.	●	●	●	●	●
Availability of a “trial assistant” (e.g. a nurse, trial coordinator, data manager, secretary) to support trial administration.					●
In-house availability of a research nurse and/or trial coordinator to support trial administration, logistics and protocol compliance.	●	●	●	●	
Trial organization					
The investigator has sufficient time and/or support from site staff to perform all tasks required for the trials.	●	●	●	●	●
The site has an adequate method to ensure that every person involved in the trial is aware of his/her delegated tasks and is informed of relevant aspects from the trial protocols.	●	●	●	●	●
The investigator has an adequate method to supervise the performance of all trial related tasks.	●	●	●	●	●
The site has an adequate method to obtain local feasibility and local approval within a reasonable time frame, in a manner that is compatible with HOVON procedures for EC approval and site initiation.	●	●	●	●	●

Criteria	Level A	Level B	Level C-HIC	Level C-SCT	Level D
The site has an adequate method to ensure the required cooperation in the trial of supporting departments (e.g. lab, pharmacy, radiology)	●	●	●	●	●
The site has an adequate method to ensure that Informed Consent is obtained from trial subjects in a manner that is in accordance with GCP.	●	●	●	●	●
The site has an adequate method to ensure that all Serious Adverse Events are reported in accordance with GCP and HOVON protocol requirements.	●	●	●	●	●
The site has an adequate method to ensure that all essential documents are filed and kept up-to-date in accordance with GCP and HOVON requirements (i.e. maintenance of an Investigator Trial File)	●	●	●	●	●
The site has an adequate method to ensure that trial data are collected and provided to the sponsor accurately and timely in accordance with GCP and HOVON requirements (i.e. CRF completion, local data management)	●	●	●	●	●
To retain echelon: active participation in HOVON trials. Active participation means that during the previous 24 months the site was open for inclusion of patients in an enrolling trial and has included at least one patient in any of those trials. With the provision that a HOVON trial suitable for the site's echelon was available to participate in during that time.	●	●	●	●	●