

CONSENSUS RECOMMENDATIONS FOR THE ROLE AND COMPETENCIES OF THE EUROPEAN PHARMACIST AND CLINICAL PHARMACOLOGIST INVOLVED IN HEMATOPOIETIC STEM CELL TRANSPLANTATION

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INTRODUCTION

The number of hematopoietic stem cell transplantations (HSCT) has expanded in the last decades and still continues to increase. To ensure safe and effective care in a vulnerable and polymedicated high-risk population, treatment should be undertaken by an experienced and fully dedicated multidisciplinary team. For many years, the role of the pharmacist has been established in many European centers. This is in part a resultant of the Joint Accreditation Committee-ISCT & EBMT (JACIE) Standards, defining the pharmacist as a key member of the HSCT team.

HSCT pharmacists are well-positioned to take a lead role in patient assessment and the development and implementation of guidelines related to pharmaceutical care. We present the activities that should be performed by pharmacists and pharmacologists with the focus on pharmacotherapy and ensuring optimal medication related outcomes from a European perspective. A distinction is made between 'mandatory' (necessary for daily practice) and 'optional' (preferably performed, whenever possible) activities.

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Recommendations for the role and competencies of the EBMT CP/P involved In HSCT

Activity	Mandatory	Optional
Pretransplant work-up and verification of conditioning regimens (check doses with respect to protocol and appropriate pharmaceutical stability in collaboration with pharmacy compounding department).	X	
Medication reconciliation at time of admission	X	
Assessment of current and past medical information/history, for example, pre-existing organ toxicity disorders that may have an effect on PK/PD (e.g., oedema in the case of renal impairment) or pose a contraindication for some treatments.	X	
Medication review to assess the appropriateness of the current medication (including allergies or possible drug interactions, use of herbal medicines).	X	
Identify and solve drug-related problems in the multidisciplinary team.	X	
Documentation of drug related problems and pharmacists interventions.	X	
Prospective medication management (evaluation of appropriate indications, effectiveness, drug interactions, dosages, co-morbidities, dose adjustments in patients with renal impairment, overweight/obesity or liver impairment...).	X	
Consideration of patient preferences, e.g., pharmaceutical formulations, especially in pediatric or elderly	X	
Identification, reporting, recording and preventing of adverse drug events and medication errors.	X	
Participation in multidisciplinary meetings and ward rounds.	X	
Medication reconciliation at time of discharge.	X	

Therapeutic drug monitoring (TDM) (drugs with narrow therapeutic window: chemotherapy, immunosuppressives, antiepileptics, anti-infectives...) (performing and/or supervising).	x	
Analysis of financial issues (reimbursement of drugs) and facilitation of access to drugs.		X
Nutrition support (enteral and parenteral)		X

HOSPITAL PHARMACY SERVICES

Activity	Mandatory	Optional
Preparation of cytotoxics	X	
Drug information service	X	
Unit-dose drug distribution		X
Computerized Physician Order Entry with Clinical Decision Support System	X	
<p>Advanced Therapy Medicinal Products</p> <ul style="list-style-type: none"> ○ To liaise with pharmacy colleagues to undertake a feasibility assessment for the use of the ATMP. ○ To ensure that hospital governance processes for ATMPs have been documented and followed. ○ To document a procedure for the use of the ATMP detailing ordering receipt, storage, preparation, administration and monitoring/follow-up, stating responsibilities of the multidisciplines involved. ○ To assess any further pharmacy capacity implications as a result of potential toxicities e.g. preparation of monoclonal antibodies, PN or intrathecal injections ○ To liaise with clinical trials and research colleagues where the ATMP is also an Investigational Medicinal Product, to ensure GCP compliance. 	X (for sites using ATMPs)	

PROCESS OF CARE

Activity	Mandatory	Optional
Development of guidelines, Standard Operating Procedures related to HSCT and supportive care.	X	
Assist in decision making for hospital formularies for HSCT patients in collaboration with other members of Medical Pharmaceutical Committee.	X	
Drug Use Evaluations (drugs, medical devices).		X

RESEARCH

Activity	Mandatory	Optional
PK-PD modeling for individualized dosing of drugs used in HSCT <ul style="list-style-type: none"> ○ Population pharmacokinetic/pharmacodynamic modeling ○ Identifying optimal exposures for most drugs in HSCT ○ Tailored dosing for optimal outcome, can be used with or without TDM ○ Comparing different exposure measures, with the goal of setting a uniform target for individualized dosing and/or TDM 		X
Development and Implementation of TDM <ul style="list-style-type: none"> ○ Developing robust and fast assays for TDM ○ Investigating the added value of TDM to patient outcomes and comparing different TDM strategies 		X
Clinical research and support in clinical trials <ul style="list-style-type: none"> ○ Available for consultation in any drug-related trial within EBMT, especially in terms of pharmacokinetics and/of pharmacodynamics. ○ Development of a central database for centers of expertise for drug level quantification. 		X

EDUCATION AND TRAINING

Activity	Mandatory	Optional
Patient education (Pretransplant visit, at time of transition: admission, discharge).	X	
Staff education (physicians, nurses, pharmacists, pharmacist technicians) – possible topics: <ul style="list-style-type: none"> ○ Supportive care, e.g. anti-infectives, cytotoxics, anti-emetics or nutrition ○ Safe handling of cytotoxics ○ Compatibility of drugs ○ Drug administration via feeding tubes ○ Central venous catheter, e.g. choice, maintenance procedures or, infusion lines ○ Compounding of cytotoxics ○ TDM ○ Handling of cellular medicines (ATMPs) 	x	
Student education.		X

QUALITY AND PROCESS IMPROVEMENT

Activity	Mandatory	Optional
JACIE accreditations requirements for pharmacists (according to the latest JACIE Standards Edition).	X	

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PHARMACO-ECONOMICS

Activity	Mandatory	Optional
Involvement in decision making of drug formularies.	X	
Pharmaco-economic analyses.		X
Involvement in cost-reduction or improved reimbursement strategies.	X	

CONCLUSION

The activities (mandatory and optional) outlined above ensure that pharmacists and pharmacologists, as member of the multidisciplinary HCT team, contribute to optimal drug therapy.