MEDICAL UNIVERSITY OF VIENNA

Training Programme (essential elements)

Clinical Practical Year (CPY)

at Medical University of Vienna, Austria

CPY-Tertial C

Clinical Pharmacology

Valid from academic year 2020/2021

Responsible for the content

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This training programme applies to the subject of "Clinical Pharmacology" within CPY tertial C "Electives". The training programmes for the elective subjects in CPY tertial C are each designed for a duration of 8 weeks.

3. Learning objectives (competences)

The following skills must be acquired or deepened in the subject of Clinical Pharmacology during the CPY. Some skills will only be possible to practice in simulation or can only be discussed in terms of their importance and possibly supported with teaching materials. In such cases this is explicitly stated.

3.1 Competences to be achieved (mandatory)

A) History taking
   1. Medication history with particular consideration of side effects and interactions with other medications; identification of medication habits of patient; also general medical history
   2. Alcohol, nicotine, illicit drug history
   3. Identifying hazardous behaviour and dangerous lifestyles
   4. Identification of inclusion and exclusion criteria and contra-indications

B) Performance of examination techniques
   5. Clinical-physical status
   6. ECG, QTc interpretation
   7. Blood pressure measurement and pulse oximetry
   8. Assessment of activities/quality of life of patient
   9. Bedside testing of blood groups
   10. Continuous monitoring of vital signs

C) Performance of routine skills and procedures
   11. Filling in prescription forms/prescribing medication
   12. Venepuncture/drawing blood
   13. Positioning a permanent peripheral venous cannula
   14. Administration of a subcutaneous injection
   15. Administration of an intramuscular injection
   16. Administration of an intravenous infusion
   17. Blood processing
   18. Urine analysis
   19. Analysing stools for blood
   20. Handling of medical laboratory equipment

D) Therapeutic measures
   21. Prescription of treatment measures for pain, nausea and hypotension
   22. Working with metered inhalers
   23. Determining the indication and use of oxygen therapy
   24. Checking drug therapy for drug interactions
   25. Identification of side effects and their management

E) Communication with patient/team
    26. Providing information to patients in an ethically correct and professional manner in compliance with legal requirements and ensuring that the patient has understood the information
    27. Checking compliance
    28. Telephoning patients in an ethically correct and professional manner
    29. Giving main information elements necessary to get informed written consent
    30. Coding of diagnoses and side effects (coding systems)
F) Documentation
    31. Source data generation for on-going monitoring and documentation of medication safety and efficacy
    32. Creating dosage tables
    33. Documentation and checking of the storage of study medication
    34. Working with case record forms
    35. Working with forms to prepare reports on medication side effects
    36. Working with local / national and international guidelines and protocols
    37. Basic knowledge of statistics, including survival curves
    38. Preparation of samples
    39. Timetable for pharmacokinetics

3.2 Optional competences

In addition to the competences that are mandatory to achieve, further competences from the following list may also be acquired.

1. Data management, data analysis
2. Determination of visual acuity and refraction
3. Using a slit lamp
4. Special analysis techniques to assess medication efficacy
5. Use of microdialysis catheter
6. Dosing, on-going monitoring and documentation of oral anticoagulation with Vitamin K antagonists (e.g. INR measurements, bedside tests)
7. Long-time ECG; long-term blood pressure measurement and interpretation
8. Interpretation of antibiogram; interpretation of urine culture findings

4. Information on verification of performance, on-going assessments

4.1 The following aspects can be assessed in the Mini-CEX:

1. Screening examination for clinical drug trial
2. Determination of health at end of study: explanation of informed consent form, history taking, clinical/physical status, taking ECG and evaluation, vital signs, planning the course of therapy (e.g.: continuous monitoring of patient safety on the first day of the trial, on-going monitoring and documentation of drug safety and efficacy during the course of the trial; where appropriate: documentation of serious adverse events or suspected unexpected serious adverse reactions, treatment of acute drug side effects, trial-specific examinations and processes)

This list can be expanded accordingly.

4.2 The following skills can be assessed in the DOPS

1. Creating dosage tables
2. Preparation of medication according to standard operating procedures
3. Correct storage of trial medication, checking and documentation
4. Correct technique for drawing blood
5. Correct injection techniques
6. Correct preparation of sample for clinical drug trials
7. Documentation of timetable for drawing blood
8. Evaluation of methodology used by student (choice of indicators, statistical method) in a project or research assignment

This list can be expanded accordingly.

5. Subject-specific details regarding the CPY tasks

The learning objectives are designed to cover the skills most commonly encountered in daily practice in the subject of Clinical Pharmacology, which every doctor should master irrespective of later specialisations.

The following CPY tasks must be completed in the subject of Clinical Pharmacology:

(A) Active tasks – mandatory component		Each 8 weeks
Case record/case review (brief)		6x
Concluding case presentation (detailed)		2x
"State of the Art" presentation on the pathogenesis, diagnosis, therapy, prevention etc. of diseases based on specific patients (20 min)		2x
Reporting of a serious adverse event (SAE) or suspected unexpected serious adverse reaction (SUSAR) (possibly based on Good Clinical Practice (GCP)		1x
Interpretation or creation of survival curves as endpoint of clinical trials		1x
(A) Active tasks – mandatory elective component	**Points**	**Each 8 weeks**
Case record/case review (brief)	4	*Elective tasks – amounting to at least 15 points from at least 2 categories*
Concluding case presentation (detailed)	8	
"State of the Art" presentation on the pathogenesis, diagnosis, therapy, prevention etc. of diseases based on specific patients (20 min)	8	
Preparation of report of distinct medical parameters	4	
Prepare referral to specialist	4	
Presentation of article in Journal Club	6	

(B) Attendance at training and professional development events – mandatory component		Each 8 weeks
Further training / intern training		2x
(B) Attendance at training and professional development events Mandatory elective component	**Points**	**Each 8 weeks**
Professional development / intern training (e.g. in-house training)	2	*Elective events amounting to at least 4 points from at least 2 categories*
Participation in state-of-the-art presentations based on specific patients	1	
Attendance at Journal Club	1	
"Morbidity & Mortality" conferences	1	
External training and professional development events per ½ day (congresses, GPMed etc.)	3	
Course attendance per ½ day (ECG course, ultrasound, suture course, burnout prevention etc.)	3	
Non-live events (e.g. Webinars)	1	

Appendix: Details of the CPY tasks in the subject of Clinical Pharmacology

Reporting of a serious adverse event (SAE) or suspected unexpected serious adverse reaction (SUSAR) (possibly based on GCP)

SAEs and SUSARs must be reported via EudraVigilance. If this is not possible, use the CIOMS form http://cioms.ch/index.php/cioms-form-i. See attached Annex.

Interpretation or creation of survival curves as endpoint of clinical trials

Background:
The production and interpretation of survival curves is of interest not only in terms of assessing overall survival and progression-free survival in oncological studies, it is also generally of interest for many time-dependent events (e.g. occurrence of combined endpoints in cardiovascular outcome studies).

To create survival curves, pre-existing datasets at the hospital (a) can be analysed, or alternatively (b) published survival curves can be reproduced.

Re (a):

1. Transfer a dataset to a suitable statistical program (e.g. SPSS) or graphics program.
2. Draw Kaplan Meier survival estimates.
3. Label the graphs.
4. Conduct log rank tests and Breslow tests.
5. Calculate hazard ratios using the Cox proportional hazard model.

Re (b):

1. Take published datasets from recent studies, measure the curves and transfer the calculated values to a suitable statistical program (e.g. SPSS) or a graphics program.
2. Draw Kaplan Meier survival estimates.
3. Label the graphs.
4. Conduct a log rank test and Breslow test.
5. Calculate hazard ratios and their 95% confidence intervals using the Cox proportional hazard model.

Formal requirements:
Datasets: In the case of existing datasets, there is no minimum size. If published datasets are used, approx. 100 data pairs (effect vs time) should be estimated per group.

Feedback: What does significance mean where the magnitude of the effect is low? Are the measured differences significant and, above all, are they clinically relevant? Is a significant therapeutic benefit probable that justifies the acceptance of possibly severe side effects?
Documentation: Copy of created survival curve.