National Training Requirements

NORWAY

Specialty

Clinical Pharmacology

(Klinisk farmakologi)

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Note: This is not a legally binding document. Any current official regulations must be obtained from the responsible National Medical Association or other organisation in charge of the training of medical specialists.

Specialist training in clinical pharmacology in Norway

The rules for specialist training in clinical pharmacology can be found on the website of the Norwegian Directorate of Health, see below.

https://helsedirektoratet.no/autorisasjon-utdanning-og-godkjenning/spesialistgodkjenning/lege/klinisk-farmakologi#krav-til-tjeneste-obligatorisk-fra-01.07.2020

Service requirements mandatory from 01.07.2020

The general provisions require full participation in the department's duty plan. If you are employed by a department with a duty roster, you must participate in the entire training to receive the service approved as a specialist training.

1. MAIN TRAINING

1.1 Service in the main specialty

4½ years of service at the approved clinical training institution for clinical pharmacology.

A minimum of 1 year must be completed at the Clinical Pharmacological Hospital Department.

1.2 Other relevant service
Up to 1 year can be replaced by:

a) research service

or

b) service in relevant specialties

or

c) service in health administration / social medicine or in general medicine.

2. Relevant Clinical Hospital Department
½ year service at the relevant clinical hospital department.

At the application for specialist approval in clinical pharmacology, the signed certificate form must be enclosed.

Notes to service mandatory from 01.07.2020

NOTE TO POINT 1a

The objectives of research in specialist training are that the doctor has competence to:

- To critically evaluate and apply the results of scientific articles in their own work.
- To be able to evaluate the workplace's or own results in diagnostic and treatment (quality assurance) using scientific methodology.

- To critically evaluate and develop systematic reviews of scientific work that have looked at diagnostics, treatment and prognostic assessment of the key diseases within the specialty.
- To disseminate research results to patients, relatives, healthcare professionals, decision makers and the general public in a suitable way.

Research services for specialist training mean service as a doctor in fellowship, in specialisation (research section) or equivalent, or work with quality improvement projects under supervision in at least 50% position.

The research service will provide counting services in relation to job vacancies. The service must be relevant to the medicine and must be documented with a certificate describing the scientific work and attesting to satisfactory service, including the fulfilment of the objectives of the research service.

The following clarifications are made:

1. Nordic Medical Doctorate (PhD) or equivalent counts with 1 year.
2. Other medical research, medical relevant research within other faculties or established research environments, including masters degree or similar, and medical doctorate from countries outside the Nordic countries, must be assessed individually. This type of research work must be documented with a guidance statement and a scientific work which must either be published in a peer review journal or attached to the application for assessment.

   From the guidance statement, time spent on active research must indicate that the doctor has the necessary knowledge of research methods and of interpretation of research results, and that the physician can critically evaluate the use of results in scientific articles.
3. Research services relevant to medicine completed prior to authorisation as a doctor may also count for this point in the rules, but must have led to an academic degree (doctorate, masters degree or similar). The stipulated service for the doctorate applies to paragraph 1. For the other degrees, the rules under paragraph 2 apply.

   Completed research line under cand. med. The study in Norway counts with 1 year.

NOTE TO POINT 1b

Service in relevant specialties includes anaesthesiology, child and adolescent psychiatry, paediatrics, immunology and transfusion medicine, internal medicine and indigenous border specialties, medical biochemistry, medical genetics, medical microbiology, neurology, nuclear medicine, oncology, pathology, psychiatry, rheumatology and drug addiction.

NOTICE TO POINT 2

Service at the relevant clinical hospital department includes anaesthesiology, child and adolescent psychiatry, paediatrics, internal medicine and indigenous border specialties, neurology, oncology, psychiatry, rheumatology, and addictive medicine.

Course training mandatory from 01.01.2018

200 hours in relevant subjects, of which 150 hours compulsory courses for the specialty of clinical pharmacology.

The compulsory courses include:

1. Pharmacokinetics, pharmacodynamics and drug monitoring
2. Clinical pharmacology in practice
3. Pharmacoeconomics
4. Drug development, drug testing and Good Clinical Practice (GCP)
5. Medical toxicology and pharmacology of drugs of abuse
6. Pharmacogenetics

In addition, compulsory courses in administration and management and compulsory online courses in specialist work are required. The Legislature's course for elected representatives may replace mandatory courses in administration and management.

Criminal law courses and criminal proceedings for forensic experts who cover the scope and content of the compulsory online course in the field of expertise can replace the online course in the field of professional work.

The transition period for new and old courses has been extended and is valid until 31.12.2017. The new course requirement will be compulsory from 1.1.2018. There is an opportunity to apply for specialist approval in clinical pharmacology based on old course requirements, new course requirements or a combination of these, for a transition period until 31.12.2017.

Note that the course "Clinical Trials / Medicine Development, Good Clinical Practice (GCP) and Medicinal Product Assessment" has changed its name to "Drug Development, Drug Testing, and Good Clinical Practice (GCP)."

THE NORWEGIAN
MEDICAL ASSOCIATION

Target description and
implementation plan for

Clinical Pharmacology

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I. Description of the specialty

Definition

"Clinical pharmacology is the science of drugs and other foreign substances and their fate and effect in humans. Clinical pharmacologists apply this knowledge in the optimisation of drug treatment and diagnostics, prevention and treatment of poisoning/abuse with drugs and other foreign compoounds."

Quality assurance of medical activities in the field

Clinical pharmacology is the only medical specialty whose main task is to work for a better and more cost effective-drug treatment. A clinical pharmacologist will contribute with his expertise to quality assurance:

a) internal and clinical pharmacology units with
- drug analytical activities
- general and special advice-giving

b) in collaboration with other medical specialties to improve the quality of drug treatment with
- information on the effects and side effects of drugs and other foreign agents
- teaching of other specialists, especially in knowledge dissemination of basic grade to clinical specialists
- clinical research on the effects and side effects of drugs (e.g. clinical drug testing)
- establishment of therapy therapies and therapy recommendations (e.g. in the work of drug committees and in collaboration with other medical specialties)
- a quality assurance committee established in clinical pharmacology that works with criteria for quality assurance, and how clinical pharmacology can contribute to quality assurance of drug treatment in general and in particular.

In particular, the analytical activity has been the work of criteria for how drug analysis should be quality-assured. There is a recommendation on this to the Dnlf[1] and Helsetilsynet[2]. Within counselling, clinical pharmacology includes established close cooperation with the Regional Medicine Information Centers (RELIS[3]) on quality assurance and further development of the activity.

Ensuring the national standard

The overall goal of specialist training in clinical pharmacology is that physicians who have undergone training should be able to function as clinical pharmacologists at central hospital level within the main functional areas specified under the specialty and field of activity. Specialists in clinical pharmacology should have an adequate overview of the effects and mechanisms of action of the registered drugs and some other foreign substances, as well as their main adverse effects, interactions and toxicity potential. Specialists in clinical pharmacology should also have good knowledge and experience in analytical clinical pharmacology and administrative skills that will enable them to lead a clinical pharmacological activity. The person should also be familiar with clinical pharmacological

[1] *Dnlf*: Den Norske Legeforening (Norwegian Medical Association).
[2] *Helsetilsynet*: Norwegian Board of Health Supervision.
[3] *RELIS*: Regionale legemiddelinformasjonssentre – Regional Medicines Information Centres.

services performed at public institutions, such as the Department of Justice and Drug Research at the Norwegian Institute of Public Health, the Norwegian Medicines Agency (SLV[4]), the Poison Information Centre and the Knowledge Centre.

Function and scope of the specialty

The definition and objectives of the field of clinical pharmacology highlight that clinical pharmacology has significant interdisciplinary medical tasks. Clinical pharmacology therefore requires general and special competence within the following six main areas:

A. Advice-giving with respect to:
1) selection of medicines, including evaluation of therapy regimens,
2) evaluation of effects and adverse reactions, single case,
3) pharmacoeconomics.

B. Drug testing
C. Drug epidemiology.
D. Analytical pharmacology with related interpretation and counselling.
E. Research.
F. Teaching and information.

Ad. A Advice-giving with regard to;
A1) Selection of drugs, including evaluation of therapy regimens. Several drugs with approximately equal effect and for use with the same indications are registered at any time. Uncritical use of drugs will have unfortunate pharmacotherapeutic and economic consequences. A conscious and systematic choice of drugs based on established criteria will contribute locally, regionally and nationally to better and more cost-effective pharmacotherapy. Regular and systematic evaluation of treatment regimens will further contribute to improved and cost-effective pharmacotherapy. For example, a clinical pharmacologist is required to perform the following functions at the hospital: Perform work at the Regional Medicine Information Centres (RELIS), participate in the medicines committee; local, central and regional, prepare and revise drug lists, evaluate and revise pharmacotherapeutic treatment regimes, as well as emergency stock of drugs and antidotes. At SLV[1], a clinical pharmacologist will be able to work with registration and registration applications of drugs, as well as with the problem of side effects and evaluation of clinical trials of drugs.

A2) Evaluation of effects and adverse reactions, single case
Individual differences in therapy response and side effects development can often be a significant medical problem and in the assessment will often require close collaboration between different medical disciplines. This work is performed primarily by RELIS[3]. Special precautions and assessments are relevant in certain patient groups, such as in children, elderly, pregnancy, breastfeeding, patients with organ failure (e.g. renal and hepatic impairment), patients who use multiple drugs, and genetic drug polymorphism. A large and increasing number of specific and potent drugs can affect patients' psychomotor functions in such a way that they can make the individual patient unfit for certain tasks. For example, a clinical pharmacist should participate in the following tasks in hospitals: Regularly maintain contact with clinical departments, e.g. in the form of active participation in clinical visits and meetings. Participate in the investigation of problem

[4] SLV: Statens legemiddelverk – Norwegian Medicines Agency.

cases and adverse reactions. In a public context, a clinical pharmacologist should be able to make expert assessments and issue statements, for example. in the legal context of investigating the effects of medicines or drugs of abuse in relation to legislation, above insurance institutions, suspected improper drug treatment or in the context of sports in suspicion of the use of "doping" agents.

A3) Pharmacoeconomics

In the next few years, the importance of proper selection of drugs, especially with regard to financing these few is becoming increasingly important. For more new drugs, one cannot expect a cost reduction for society. However, a reduction in suffering and disease will be required as a background for the registration of new drugs.

Evaluation and quantification of efficacy and safety (e.g. endpoint and quality assays, etc.) in relation to financial assessments will be important and priority tasks for clinical pharmacologists.

Regarding the choice of older medicines, the authorities have already introduced various measures (e.g. reference prices). Further measures as part of the savings on drug costs are expected. It will be important that the choices made will be made on the advice of current clinical specialists and clinical pharmacologists. This applies both at regional and national level.

When selecting medicines at hospital level, special therapeutic procedures in the future could be established on the basis of primary economic criteria. In this process, clinical pharmacologists will have a central place in assessing and taking care of the overall and medical aspects.

Ad. B, C. Drug testing, drug epidemiology

There is always a considerable number of new drugs for testing on patients in and outside health institutions with the aim of obtaining professional documentation for registration applications for medicinal products. Comparative effect / side effects studies of both unregistered and registered drugs will provide results that provide the basis for selecting better drugs and treatment regimens. The preparation of local, regional and national consumption statistics for pharmaceuticals, individually, in groups or in total, may be important corrections for current pharmacotherapeutic practices.

For example, a clinical pharmacologist is expected to be able to participate in occupational tasks in hospitals, pharmaceutical industry and SLVs as regards the planning, implementation and interpretation of clinical trials and investigations of medicinal products in patients in health institutions and in general practice. A clinical pharmacologist will also have important tasks in follow-up work and investigations after drugs have come into general use.

Ad. D Analytical pharmacology and related interpretation

Drug analyses as part of therapy control have helped improve pharmacotherapy for a variety of drugs, e.g. antiepileptics, antiarrhythmics, digitalis glycosides, theophylline, aminoglycosides, lithium, antidepressants and other psychotropic drugs, cytostatics and immunosuppressants. In the future, drug analyses in the field of therapy control will also be of great importance; especially important for medicines with narrow therapeutic window, and in patients with complicated conditions such as, e.g. genetically-conditioned drug polymorphism, age variation, pregnancy, certain organ diseases and when using multiple medicines or drugs of abuse.

Also in the case of misuse of drugs and other substances in different contexts, e.g. substance abuse and doping in sport, qualitative and quantitative measurements in biological material are important both in diagnostics and treatment. Also in relation to

legislation, e.g. Road Traffic Act and Penal Code, detection and quantification of medicines / drugs of abuse in biological materials, including interpretation and advice, will be important. The need for such services seems to increase in scope.
In case of acute inoculations, self-inflicted and accidental, identification of substances with subsequent determinations of blood concentrations is of importance. More patients die of poisoning outside hospitals than in hospitals. The mortality rate of hospitalised patients with acute inhalations has increased at some hospitals. Identification of drugs and certain other substances in biological materials, proper general treatment, active removal of substances by pharmacological principles and use of specific antidotes, will help improve the prognosis as well as shorten the length of time for the individual patient in the hospital. Also with other inoculations, subacute and chronic, detection of substances contaminating the body will be important.
The complexity of analytical pharmacology, biotransformation and the effects of drugs and other substances requires in-depth knowledge, analytical as well as interpretative, in conjunction with therapy control, abuse or inoculation. It is therefore important that the analysis of drugs and other substances is subject to strict quality control and that analytical data are not detached from the knowledge of pharmacology, toxicology and the problem of abuse. Use of low specificity methods can lead to serious problems.
A clinical pharmacologist is thus expected to possess competence so that he can, for example, exercise a sound business in hospitals, in the legal context and in society in the areas of therapy control, drug toxicity, substance abuse and drug abuse.

Ad. E Research
The extensive use of drugs and other substances foreign to the body, the significant individual variation in response to standard dosage, as well as abuse potentials for a variety of substances, suggest that research in clinical pharmacology must have a central place. Research tasks in clinical pharmacology will include: Epidemiological studies of consumption, side effects, poisoning and abuse, clinical trials of drugs, development and evaluation of analytical methods for both new and "old" drugs, establishing reference areas, and research on drug dependence. It will be important to study the causes of individual variations in drug response, including those due to pharmacokinetic and pharmacodynamic variations in healthy and sick subjects, as well as different gender and age groups.

Ad. F Teaching and information
In order to make an adequate choice of medicines for use in treatment, in general practice or in specialised clinical activities, knowledge in clinical pharmacology is required. Therefore, teaching in clinical pharmacology must be given both during primary and postgraduate education to several types of healthcare professionals.
A clinical pharmacologist should therefore be able to teach students (doctors, nurses and other healthcare professionals), plan and conduct organised postgraduate education in the form of courses and lectures for doctors, pharmacists, nurses and other healthcare professionals and inform about medicines and other substances in the form of arranging therapist conferences and regularly publish bulletins about pharmacotherapy, side effects and new developments in the field.

Fagets plass/nivå i helsetjenesten

1. The place of the specialty in the health service

The specialty of clinical pharmacology has three main components; one social-medical, one laboratory-medical and one clinical-medical. Clinical pharmacology also has important tasks related to primary health care and prevention activities. Central to this work is the desire for improved pharmacotherapy with the aim of reducing side effects and improving

the patient's drug treatment. Clinical pharmacology also has important tasks related to the prevention of substance abuse and suicidal problems.

2. The target area of the specialty

Clinical pharmacology has significant medical interdisciplinary tasks and cooperates extensively with clinical specialists such as, e.g. internal medicine, anaesthesiology, oncology, neurology, psychiatry and general medicine. Clinical pharmacological activities have a natural place within the hospital community, and clinical pharmacological departments/sections have been established at all 5 regional hospitals, at the National Institute of Public Health and Diakonhemmet Hospital. Clinical pharmacological units should also be established at most major central hospital hospitals and at psychiatric institutions. Other activities where clinical pharmacological competence should be established include: SLV, Poison Information, Knowledge Centre and in the pharmaceutical industry.

3. Preventive work

Improper use of drugs is a burden on the healthcare system and has a major economic impact on society.

Of the issues that are particularly problematic are:

- Drug side effects
- Drug poisoning (accidental and with suicidal intent)
- Drug and drug abuse
- Polypharmacy.

The specialty of clinical pharmacology has as one of its most important tasks to help reduce the negative aspects of drug use. Clinical pharmacologists will be important partners, and in many contexts one of the main contributors, to conduct preventive work aimed at reducing the "harmfulness" of pharmacotherapy. Increased efforts in this area could contribute to significant economic cost savings for society.

II. Learning objectives for specialist training in clinical pharmacology

General learning objectives

It is required that the person who wants to be a clinical pharmacist must:

- acquire a considerable amount of theoretical knowledge
- learn skills in analytical activities
- be able to combine theoretical knowledge with practical issues aimed at the tasks the clinical pharmacologist should perform
- develop attitudes and knowledge that allow for adequate theoretical and practical consideration of the individual patient's specificity, health and social issues, and to enable effective and trustworthy interdisciplinary cooperation between doctors, nurses and healthcare professionals in general.

Specific learning objectives

After graduating, the clinical pharmacist must have acquired sufficient knowledge in:

a) General, basic and clinical pharmacology
b) Applied clinical pharmacology

Ad a) General, basic and clinic pharmacology

The acquirement of theoretical knowledge should be aimed at specialists in clinical pharmacology to be familiar with and be able to explain

- general pharmacology with an overview of the effects and mechanisms of action of registered drugs and some other substances, as well as knowledge of their main adverse events, interactions and toxicity potential,
- principles in pharmacodynamics and pharmacokinetics
- causes of individual variations in the response to drugs and other foreign substances by equal dosage,
- how physiological/pathophysiological changes may affect pharmacokinetics and pharmacodynamics of drugs,
- methods of analysis and methodology for medicinal products and other foreign substances in biological material,
- clinical trials of medicines,
- statistics,
- the relationship between drugs and other foreign substances with general provisions on prescribing and handling, as well as relationships with legislation,
- legal-toxicological matters related to the use and abuse of legal and illegal substances
- ethics of medical research.

Ad b) Applied clinical pharmacology

The candidate will be trained to apply his basic knowledge so that he/she can use it in connection with:

- drug analyses with associated interpretation,
- individualised and general pharmacotherapy,
- drug epidemiology and economics, e.g. through work in the pharmaceutical committee,
- clinical drug testing,
- evaluation and investigation of adverse reactions,
- drug intoxication,
- abuse of medicines and drugs of abuse,
- toxicological assessments,
- age-related aspects, especially aimed at paediatric and geriatric conditions,
- drug information including the organisation and implementation of therapy conferences,
- organise and carry out relevant research tasks,
- organise and implement educational programs for students and in connection with further education of health personnel,
- through research and other training in scientific thinking, acquire a factual, critical attitude towards clinical documentation of therapeutic effects and other effects.

Acquisition of knowledge and skills

Training in clinical pharmacology is expected to last the professional life. An important goal of specialist training is therefore that the candidate should learn good and effective study techniques. The candidate must bear the responsibility for adequate knowledge acquisition, but it is the responsibility of the training institution to assume a major

responsibility in the form of facilitation and guidance in implementing this knowledge acquisition. Consequently, meetings and colloquia will be held regularly in the training institution, with particular attention being paid to the training of candidates in clinical pharmacology. The candidate will be guided in the choice of textbooks and the selection of journals. He/she will also be given regular opportunities to make assessments of the literature he/she has undergone.
On a national basis, courses that are mandatory and regularly deal with the most important principles in basic and clinical pharmacology, as well as courses with opportunities for specialisation, must be arranged regularly.

Progression in acquisition of knowledge and skills

In the event of the appointment of candidates in the training position, the candidate shall be informed of what training programs are waiting and what obligations are imposed on him/her.
The candidate shall be encouraged as early as possible to start him/her own knowledge acquisition and the departmental management is responsible for the candidate being included in the above-mentioned practical tasks in such a way that progressive development of skills for independent work as well as the ability for interdisciplinary cooperation are developed.

Evaluation of the acquisition of knowledge and skills

Candidates
For the candidate, evaluation methods for teaching and knowledge acquisition should be prepared. Written records must be kept of which practical and theoretical assignments and which compulsory courses and any specialisation course the candidate has participated in. In the long term, guidelines for examinations should be drawn up that can prove that the candidate has achieved an adequate level of knowledge.

The training institution
Evaluation of the activities of the approved training institutions must be evaluated regularly so that the candidate is sure that the training and practice given at the institution is in accordance with the intentions of the training program.

Implementation plan for training
The formal requirements for specialist training in clinical pharmacology are stated in the Yearbook of the Norwegian Medical Association.

In general
The training of specialists in clinical pharmacology must aim to ensure, as far as possible, that anyone who is granted specialist approval in clinical pharmacology must have sufficient theoretical knowledge, practical skills and attitudes that make the doctor fit to act as a specialist in clinical pharmacology in overall position or equivalent in or outside the hospital.

The main program
The aim of the main training in clinical pharmacology is to provide the candidate with general and special skills, as well as knowledge within the main areas specified in the section “Scope and function of the specialty”, and detailed under “Specific learning objectives”. According to the Medical Association’s provisions, at each training institution there must be a training committee, a teaching program for the department and an individual training plan for the individual candidate.

The training candidate must have a supervisor who assists the candidate in completing the training plan, and an internship program of at least 2 hours per week must be added.

The training candidate's duty roster is set up in such a way that the candidate is given time to:

- acquire practical knowledge and skills
- acquire theoretical knowledge
- research
- teaching of students
- participation in collaboration with other specialties and experience in the field of research and information about medicines.

New training candidates should participate in the department's overall work tasks in the first instance of the service with an approved specialist in clinical pharmacology and/or competent staff in the department who can provide satisfactory training and introduction to the department's work. Later, the training candidate should regularly and adequately participate in the department's routine tasks. Regularity should be sought so that the duty roster provides room for all of the above tasks.

Guidance

Good medical specialist training is an important foundation for good medical practice. Quality assurance of specialist training at all levels is therefore a key task and is based on accepted standards and learning objectives.

Using the goal description for specialist education, one tries to provide a standard for the specialist education's content and goals.

In order for the aims of the goal description to be complied with, it is of the utmost importance that the individual training institutions draw up general and individual training plans. In order to ensure that the completed specialists maintain the goals set for sound clinical pharmacological specialist activities, the individual supervisor's responsibility is a major responsibility. For each candidate, a supervisor shall be appointed at the commencement of the service. The supervisor shall ensure that an individual training plan is drawn up for the candidate. The supervisor shall be available in the follow-up of the candidate in such a way that he/she is continuously informed of how the candidate's training program is in relation to the training plan. Furthermore, in the meetings between supervisor and candidate, as well as in connection with more departmental work and external activities, the supervisor must ensure that the candidate acquires the necessary knowledge, skills and attitudes that a specialist in clinical pharmacology should have.

Internal teaching

The candidate's duty roster must include a minimum of 2 hours of internal teaching per week.

Internal teaching should include:

a) Specialty colloquia.

At these teaching meetings there should be a structured review of the core pensum. For example, at these meetings you can review relevant textbooks, possibly chapters from these.

In the first phase of the training period, the general relationship with pharmacokinetics and pharmacodynamics should be reviewed. Later, the individual drugs should be reviewed.

b) Literature meetings / case problem meetings.

The purpose of these meetings is that the candidate will receive training in evaluating scientific articles as well as investigated, often interdisciplinary case problems.

Course training
A duty roster must be set up so that the training candidate is given the opportunity to attend a sufficient number of courses. The candidate is required to attend the compulsory courses. The purpose of these courses is to provide knowledge about the main elements of the specialty. The compulsory courses are presented with a final written exam, where the grades are passed/failed. In order for the courses to be approved as part of specialist training, the candidate must document passed courses with the grade passed. The purpose of the compulsory courses, with a passing grade test, is to ensure that the candidate has the necessary minimum theoretical knowledge.

Subsidiary training
Clinical pharmacology has significant interdisciplinary medical tasks. It works extensively with other clinical specialties, such as, for example, internal medicine, anaesthesiology, oncology, neurology, paediatrics, psychiatry and general medicine.
It is therefore of paramount importance that the specialist training entails a requirement for clinical services so that the specialist in clinical pharmacology has a certain level of competence in clinical activities. When choosing a side training it is therefore important that the candidate chooses clinical subjects where pharmacotherapy has a central place in the treatment plan. It is considered an advantage if the subsidiary training is taken towards the end of or after completed main education.

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