MINISTRY OF HEALTH OF UKRAINE
ODESA NATIONAL MEDICAL UNIVERSITY

Pharmacy Faculty

Department of General and Clinical Epidemiology and Biosafety with course in Microbiology and Virology

Syllabus of course "VACCINOLOGY. TOOLS AND TECHNOLOGIES"

Volume:	Total number of hours: 90 hours, 3 credits Semester: V - VI 3rd course
Days, Time, Place:	According to the Schedule Department of General and Clinical Epidemiology and Biosafety with course in Microbiology and Virology, academic discipline "Microbiology with Basics of Immunology". Odesa, 1 Knyazivska str., rooms 1-6
Teacher(s)	Hruzesvkyi O.A., MD, Doctor of Science, full professor; Associate professors: Holovatiuk O.L., MD, PhD, Koltsova I.G., MD, PhD, Kurtova M.M., MD, PhD, Shevchuk H.Y., PhD; Assistant professors: Denysko T.V., Dubina A.V, MD, Kahliak M.D., Tabulina A.M., Tarasov Y.V., MD
Contact information	*Phone:* Shevchuk Hanna, Head of studies 093-419-96-77 Dubina Anzhela, responsible for the organizational and educational work of the department 067-428-63-43 Cheban Maya, laboratory assistant 048-753-09-81 E-mail: onmedumicrobio@onmedu.edu.ua; Offline consultations: Thursday – 14.00 - 16.00; Saturday – 9.00 - 13.00; Online consultations: Thursday – 14.00 - 16.00; Saturday – 9.00 - 13.00; The link to the online consultation is provided to each group during the classes separately.

COMMUNICATION

Communication with students will be carried out in the classroom (in person).

During distance learning, communication is carried out through the Microsoft Teams platform, Moodle, as well as through e-mail correspondence, Viber and Telegram messengers (through groups created in Telegram for each group, separately through the group head).

ANNOTATION OF THE COURSE

The subject of study of the discipline is vaccine prophylaxis, stages of vaccine development and clinical trials, approaches to assessing their safety, quality and efficacy. The course provides an analysis of current issues in vaccinology through the prism of various vaccine-controlled diseases..

Prerequisites and post-requisites of the discipline (place of the discipline in the educational program):

Prerequisites: Latin, medical biology, medical and biological physics, biological and bioorganic chemistry, human anatomy, histology, cytology and embryology, physiology.

Post-requisites: Hygiene, epidemiology with a course of evidence-based medicine, pathophysiology, pathomorphology, clinical immunology and allergology, infectious diseases with children's infectious diseases, internal medicine, general surgery and other clinical disciplines.

The purpose is: to master the knowledge about the classification and characterization of vaccines, stages of their development and clinical trials, approaches to assessing the safety, quality and efficacy of vaccines, modern platforms and approaches to vaccination.

The tasks of the discipline:

1. Teaching how to analyze the results of clinical trials of vaccines and determine their effectiveness.
2. To form knowledge of the main classes of vaccines and their characteristics.
3. To teach to critically analyze the ethical aspects of vaccination and identify the best strategies for solving ethical problems.
4. To develop the ability to identify possible risks and adverse events after immunization.
5. To develop the ability to apply vaccine knowledge to explain the importance of vaccination and promote the conscious acceptance of vaccines in the public.

Expected result:

As a result of studying the discipline, the student has to:

Know:

- main classes of vaccines and their characteristics;
- main stages of vaccine production;
- mechanism of action of vaccines and their impact on the immune system;
- the role of vaccination in global health.

Be able:

- to analyze the results of clinical trials of the vaccine and determine its effectiveness;
- to identify possible risks and adverse events after immunization;
- to critically analyze the ethical aspects of vaccination and determine the best strategies for addressing ethical issues;
- to apply vaccine knowledge to explain the importance of vaccination and to promote the conscious acceptance of vaccines in the public;
- to apply innovative vaccination strategies.

DESCRIPTION OF THE COURSE

Forms and methods of teaching

The course will be presented in the form of practical lessons (30 hours), organization of independent work of students (60 hours).

Teaching methods: conversation, explanation, discussion, discussion of the acute issues; visual methods: illustration (including multimedia presentations); testing.

The content of the discipline

Theme 1 Theme 1: Fundamentals of vaccinology. Immunological basis of vaccine prophylaxis.

Theme 2. Classification and comparative characteristics of vaccines.

Theme 3. Smallpox eradication experience: immunization, strategies for control and eradication of vaccine-controlled diseases.

Theme 4. Stages of development and clinical trials of vaccine candidates.

Theme 5. Ethical aspects of vaccine development and vaccination.

Theme 6: Current GMP (good manufacturing practices) standards for the production of vaccines and antibodies.

Theme 7. Monitoring of vaccine safety, evaluation of their quality and efficacy.

Theme 8: Adverse events after immunization: classification, evidence and causation.

Theme 9: Influenza: the problem of creating a new vaccine every year.

Theme 10. Vaccines against SARS-CoV 2: Where are we now?

Theme 11: Vaccines against Ebola virus: an overview of current approaches.

Theme 12: Tuberculosis: BCG, new vaccines and biomarkers for vaccine trials.

Theme 13: Cancer vaccines as promising immunotherapeutic agents: platforms and current progress.

Theme 14: Vaccines that are yet to be developed and implemented. Vaccines and response to infectious disease outbreaks.

Theme 15: Challenges related to HIV vaccines.

List of recommended literature:

Main:

1. Abbas, A., Litchman, A. H. & Pillai, S. Basic Immunology - 6th Edition. (Elsevier Ltd, 2019).

2. Anantharyan R. Jayaram Paniker C. K. Textbook of Microbiology. 12-th Edition.- Orient Longman, 2022.

3. Male, D., Peebles, S. & Male, V. Immunology. (2020).

Additional:

4. Dudley MZ, Halsey NA, Omer SB, Orenstein WA, O'Leary ST, Limaye RJ, Salmon DA. The state of vaccine safety science: systematic reviews of the evidence. Lancet Infect Dis. 2020 May;20(5):e80-e89. doi: 10.1016/S1473-3099(20)30130-4. Epub 2020 Apr 9. PMID: 32278359.

5. Jalilian H, Amraei M, Javanshir E, Jamebozorgi K, Faraji-Khiavi F. Ethical considerations of the vaccine development process and vaccination: a scoping review. BMC Health Serv Res. 2023 Mar 14;23(1):255. doi: 10.1186/s12913-023-09237-6. PMID: 36918888; PMCID: PMC10013982.

6. Schrager LK, Harris RC, Vekemans J. Research and development of new tuberculosis vaccines: a review. F1000Res. 2018 Nov 1;7:1732. doi: 10.12688/f1000research.16521.2. PMID: 30613395; PMCID: PMC6305224.

7. Gross L, Lhomme E, Pasin C, Richert L, Thiebaut R. Ebola vaccine development: Systematic review of pre-clinical and clinical studies, and meta-analysis of determinants of antibody response variability after vaccination. Int J Infect Dis. 2018 Sep;74:83-96. doi: 10.1016/j.ijid.2018.06.022. Epub 2018 Jul 5. PMID: 29981944.

8. Liu J, Fu M, Wang M, Wan D, Wei Y, Wei X. Cancer vaccines as promising immuno-therapeutics: platforms and current progress. J Hematol Oncol. 2022 Mar 18;15(1):28. doi: 10.1186/s13045-022-01247-x. PMID: 35303904; PMCID: PMC8931585.

CRITERIA EVALUATION

Ongoing control: individual survey on the theme, testing, evaluation of practical skills, solving situational problems, the ability to analyze and interpret research results and correctly draw reasonable conclusions, evaluation of activity in the classroom.

Criteria of ongoing assessment at the practical class

Score	Assessment criterion
Excellent «5»	The student takes an active part in practical classes, demonstrates deep knowledge, gives complete and detailed answers to questions. Takes an active part in discussing problem situations, demonstrates good skills and abilities in performing practical tasks, correctly evaluates the results. Test tasks are completed in full.
Good «4»	The student participates in practical classes; has a good command of the material. Demonstrates the necessary knowledge, but answers questions with some mistakes; participates in the discussion of problem situations. Test tasks are completed in full, at least 70% of answers to questions are correct.
Satisfactory «3»	The student sometimes participates in practical classes; partially speaks and asks questions; makes mistakes when answering questions; shows passive work in practical classes. Demonstrates skills and abilities in performing practical tasks, but evaluates the results obtained insufficiently fully and accurately. Testing is completed in full, at least 50% of answers are correct, answers to open questions are not logical, with obvious significant errors in definitions.
Unsatisfactory «2»	The student does not participate in the practical lesson, is only an observer; never speaks and does not ask questions, is not interested in learning the material; gives incorrect answers to questions, demonstrates insufficient skills and abilities, cannot cope with practical work and evaluation of the results. Testing is not completed.

Final control: Credit is given to an applicant who has completed all the tasks of the work program of the discipline, actively participated in seminars and has an average current grade of at least 3.0 and has no academic debt.

Possibility and conditions for receiving additional (bonus) points: not provided.

INDEPENDENT WORK OF STUDENTS

Independent work involves preparation for each seminar, independent study of a certain list of topics or topics that require in-depth study. Questions on topics assigned for independent study are included in the control measures.

COURSE POLICY

Policy on deadlines and retakes:

- Unexcused absences will be made up as scheduled by the teachers on duty.
- Excused absences are made up on an individual schedule with the permission of the dean.

Policy on academic integrity:

It is obligatory to observe academic integrity by students, namely independent performance of all types of work, tasks, forms of control provided by the work program of this discipline:

- references to sources of information in case of using ideas, developments, statements, information;
- compliance with copyright and related rights legislation;
- providing reliable information about the results of their own educational (scientific) activities, used research methods and sources of information.

Unacceptable in educational activities for participants in the educational process are:

- the use of family or official ties to obtain a positive or higher grade during any form of control of learning outcomes or advantages in scientific work;
- use of prohibited auxiliary materials or technical means (cribs, notes, micro-headphones, phones, smartphones, tablets, etc.) during control assessments;
- passing the procedures for controlling the results of training by fictitious persons.

For violation of academic integrity, students may be brought to such academic responsibility:

- lowering the results of the assessment of control work, assessment in the classroom, test, etc;
- repeated passing of assessment (control work, test, etc.)
- appointment of additional control assessments (additional individual tasks, control works, tests, etc.);
- conducting an additional check of other works of the offender's authorship.

Policy on attendance and lateness:

Uniform: medical gown that completely covers the outer clothing, or medical pajamas, cap, mask, change of shoes.

Equipment: notebook, pen.

Health status: students with acute infectious diseases, including respiratory diseases, are not allowed to attend classes.

Lateness to classes is not allowed. A student who is late for the lesson may attend it, but if the teacher has put "ab" in the register, they must made it up in the general order.

Use of mobile devices:

The use of any mobile devices is prohibited. In case of violation of this paragraph, the student must leave the class and the teacher puts "ab" in the register, which they must made out up the general order.

Mobile devices can be used by students with the permission of the teacher if they are needed to complete the task.

Behaviour in the classroom:

The behavior of students and teachers in the classroom must be working and calm, strictly comply with the rules established by the Regulations on Academic Integrity and Ethics of Academic Relations at Odesa National Medical University, in accordance with the Code of Academic Ethics and Relations of the University Community of Odesa National Medical University, the Regulations on the Prevention and Detection of Academic Plagiarism in the Research and Educational Work of Higher Education Students, Researchers and Teachers of Odesa National Medical University.