<table>
<thead>
<tr>
<th>Vak: Clinical Trials and Health Care (Periode 2)</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vak: Infectious Diseases and Vaccine Development (Periode 3)</td>
<td>2</td>
</tr>
<tr>
<td>Vak: Key Strategies in Disability and Neuropathy (Periode 1)</td>
<td>4</td>
</tr>
<tr>
<td>Vak: Tailoring Medicine and Telemedicine (Periode 2)</td>
<td>6</td>
</tr>
</tbody>
</table>
Clinical Trials and Health Care

<table>
<thead>
<tr>
<th>Vakcode</th>
<th>AB_1043 ()</th>
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<td>Periode</td>
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<td>Faculteit</td>
<td>Fac. der Aard- en Levenswetenschappen</td>
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<tr>
<td>Coördinator</td>
<td>dr. N. Blignaut-van Westrhenen</td>
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<tr>
<td>Examinator</td>
<td>L.A. Akrong</td>
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<tr>
<td>Docent(en)</td>
<td>dr. T.J. Schuitmaker-Warnaar</td>
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<tr>
<td>Lesmethode(n)</td>
<td>Werkgroep, Practicum, Hoorcollege</td>
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<td>Niveau</td>
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Doel vak
- Acquire insight into the process and wider context of clinical trials.
- Obtain knowledge and insight into the juridical and financial factors concerning clinical trials and innovation processes.
- Gain insight into societal and political responses to scientific uncertainties surrounding clinical trials, safety and innovative health interventions.
- Gain insight in the need for and practice of a systemic perspective on innovation.
- Be able to form lines of argumentation and participate in debate in the context of specific cases and team assignments.
- Be able to apply practical and theoretical skills, such as conducting a literature study, critically analysing various scientific publications, hypotheses and arguments, and justifying and presenting findings both orally and in writing.
- Get acquainted with interdisciplinary (gamma-beta) research.

Inhoud vak
Clinical trials are a crucial step in the development process of many health interventions (e.g. new drugs, diagnostics, medical devices and therapy protocols). By setting up carefully designed quantitative experiments, new interventions are tested for safety, efficacy and cost-effectiveness on human beings (initially healthy volunteers, later patients). In many countries clinical trials are required before the national regulatory authority allows the drug, device or therapy to be marketed and used on patients. Clinical trials are, however, not unproblematic. There are various accounts of prematurely terminated trials because of serious side effects or high death rates in the interventional arm of the study. Furthermore, some of the tested interventions have raised ethical concerns, because they involved the use of a controversial technology like stem cell therapy, or were conducted in a developing country without appropriate safety measures. There are also difficulties encountered in recruiting sufficient numbers of volunteers in experiments. Frustrated by being only treated as ‘subjects’, patients increasingly demand a ‘say’ in the design and implementation of clinical trials. From a governmental perspective, the former innovative power that improved health care is now more and more seen as a financial burden. And last, there are severe problems for the industry that is behind these clinical innovations. The pharmaceutical industry is facing tremendous pressure, not only from payers, but as a result of public perception, regulatory hurdles, and the intricacies of research and development (R&D). Overall, medical (and especially drug)
development has been stagnant in terms of innovation, and failure to innovate the developmental process itself will render the “Big Pharma” model unsustainable. How to deal with this?

Central in this course is the idea that a systemic perspective, i.e. the involvement of relevant stakeholders in the innovation process, can benefit both quality and successful implementation of new products. In the course, the ins and outs of the process of clinical trials are discussed. How do you do a trial; what actors and factors are involved? Based on that, recent debates around clinical trials are highlighted. How can we assess and manage risks if there is uncertainty about how the risks look like? What precautions should we take from a medical and societal perspective before we decide to (not) start a clinical trial? Can, and should, patients be involved in the decision process around clinical trials?

In teams of four to six students, you search and collect research data from the lectures and from scientific papers and build a portfolio. Every workgroup meeting, debates will be held based on the gathered information, thus sharpening your discussion skills and deepening your knowledge about the latest scientific developments and the role of clinical trials to protect patients, consumers and societies.

Onderwijsvorm
Tuition methods include lectures, work groups, a group project and self-study.

The different elements have the following study time:

- lectures 24 hours
- work groups 16 hours
- group project 32 hours
- self study (including portfolio assignment and exam) 98 hours

Toetsvorm
The final grade is the sum of the exam (60%) and the group-project portfolio and research assignment (40%). Both need to be passed, because both test different competences.

Literatuur
On Canvas you will find literature for every lecture. This literature will become part of your portfolio. For your research assignment you need to find literature yourself.

Overige informatie
Guest Lecturers:
- Henk Jan Out (UMCN)
- Jolanda de Boer (CVZ)
- Janine Sikkens- van de Kraats (VUMC)
- Pim de Boer (Astmafonds)

More information: T.J.Schuitmaker@vu.nl

Infectious Diseases and Vaccine Development

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Doel vak
Acquire basic knowledge and insight in:
• Infectious diseases, diagnosis, vaccines, vaccination and vaccine immunology
• The history and future of the Dutch national vaccination program
• Vaccines in International Public Health and the role of international organizations
• Vaccine Research & Development, Production and Quality Assurance
• Regulatory aspects in vaccine development, production and safety monitoring
• Public opinions, communication and scare stories
• Vaccination policies for special groups such as of travelers, immigrants, soldiers, and women during pregnancy and lactation

Acquire skills in analyzing and presenting a vaccine and vaccination strategy for one specific infectious disease (group assignment)

Inhoud vak
This course gives insight into the past, current and future preventive health care concerning control of infectious diseases with a focus on vaccination. It will be a mixture between biomedical sciences and health policy and management.
First, we will refresh your knowledge on infectious diseases and immunology as the basis for vaccinology. Diagnostics, essential for testing of vaccine efficacy and prevalence of diseases, are also discussed. We further focus on the research & development and manufacturing of vaccines, including quality control and quality assurance. The safety monitoring of vaccines will get special attention. We will address a number of infectious diseases that can be prevented by vaccines in national and international context. Hence the Dutch National Vaccination Program will be discussed in detail, as will the role of vaccines in International Public Health. We will analyze the Dutch vaccination program and the role of key actors such as the government, the Dutch Health Council and the National Institute of Public Health and Environment (RIVM). The future outline and challenges of the Dutch vaccination program are discussed in detail, including how public opinion affects vaccination policies.
To put acquired knowledge into practice, all students will be involved in a group assignment, studying one particular vaccine against a specific infectious disease. The results of these group assignments are to be reported in a presentation and a written report.
At the end of the course students will get the opportunity to visit the Vaccine Unit of the RIVM in Bilthoven, for discussion on specific subjects of interest with scientists involved with the implementation of the Dutch vaccination program.
Onderwijsvorm
Lectures, group assignment, presentation, essay, discussion, excursion, self-study
The group assignment is compulsory.
Contact hours: lectures 18 hrs; plenary group work 4 hrs; excursion 8 hrs; self-study approx. 80 hrs.

Toetsvorm
Individual exam (80%) and group assignment presentation and report (20%). Both parts must at least be sufficient (6 or higher)

Literatuur
Lecturers may make further readings available on Canvas.

Aanbevolen voorkennis
Basic knowledge about the pathogenesis of infectious diseases, including microbiology and immunology

Doelgroep
Part of the minor Biomedical and Health Interventions. Optional course for a variety of minors, highly recommended for students that consider following the master Management Policy Analysis and Entrepreneurship or the master specializations International Public Health or Infectious Diseases.
This minor course requires a minimum of 25 participants to take place.

Intekenprocedure
Enrollment through Canvas.

Overige informatie
Lecturers:
Prof. Dr. Han van den Bosch
Dr. Bernard Ganter
Margot Triebels, MSc
Guest Lecturers:
Dr. Wil Hilgersom (LAREB)
Prof. Dr. Pieter van Thiel (Center for Tropical and Travel Medicine, AMC)
Dr. Bettie Voordouw (RIVM)
Prof. Dr. Virgil Schijns (WUR)
Various scientists at RIVM (Bilthoven) during site visit

Basic knowledge about the pathogenesis of infectious diseases, including microbiology and immunology

Key Strategies in Disability and Neuropathy
Doel vak
• Gain insight into the issues and intervention strategies concerning common causes of disability, using neuropathy as a model
• Gain insight into strategies for the prevention of disabilities, rehabilitation and inclusion
• Gain insight into various philosophical ideas about the meaning of disability and diversity: how do people experience disability, and what does this mean for the choices that matter (in management, policy and personal life)
• Gain insight in the rights of persons with disabilities
• Gain insight into how these ideas are influenced by innovations in the field of biomedical sciences
• Practice research skills during the workgroups (participating in scientific discussions, formulation of research objectives, literature research, abstracting, summarising and giving feedback of findings)
• Develop skills in formulating lines of argumentation in written and visual form through a photo essay

Inhoud vak
All over the world there are persons with disabilities who experience difficulties participating in their societies. The scale of this problem is highlighted by the World Health Survey and the Global Burden of Disease, both from 2004, which show the estimated prevalence of disability to be 15.6% and 19.4% respectively (WHO 2011).
This course looks at issues surrounding disabilities, taking into account multiple perspectives, like health, social and rights. Herein we will illustrate the theoretical views on disability with disease specific examples, showing the diversity and similarities in disability issues. This would concern e.g. neuropathy caused by diabetes, leprosy, and buruli ulcer and other forms of disability like intellectual disability, autism, and ADHD. The course reviews relevant interventions and various technologies used to address health, social and environmental problems related to disability. During the course you investigate questions such as ‘How do different worldviews (including my own) influence how people see disability, ‘differentness’ and diversity? ‘What does an ideal world look like with regard to diversity?’ ‘What is the meaning of this for my own and other people’s lives?’ During the 20th century, developments and innovations in health and life sciences have resulted in an exponential growth in scientific knowledge about man, society and environment. The idea that we know who we are seems to increase, but is this truly the case? For example, what does a disability mean for our identity and our image of human nature? Innovations bring forth possibilities for new interventions and technological gadgets (e.g. bionic prosthetics, cochlear implants, microchips that enhance intelligence), but how do we select and use these? Who decides what is appropriate for whom, in particular in the majority world?
In this course you learn to reflect on various philosophical perspectives related to disability and diversity and think about your
Onderwijsvorm
- Lectures (20 hours)
- Work groups (24 hours)
- Photo essay workshop and Q&A (6 hours)
- Self-study (remaining hours)

Toetsvorm
- Individual exam (60%)
- Group assignment: photo essay (30%)
- Participation in workgroups (problem-based learning) (10%)
All three parts need to be passed individually.

Literatuur
Articles via Canvas and exchanged via students

Doelgroep
Bachelor students from Biomedical Sciences, Health & Life, Health Sciences, bachelor programs in the natural sciences and similar bachelor programs that participate in the minor Biomedical and health interventions or in the minor Global Health.

Overige informatie
More information: Dr. Ruth Peters (r.m.h.peters@vu.nl)

Tailoring Medicine and Telemedicine

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<td>Lesmethode(n)</td>
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Doel vak
Knowledge:
• Gain insight in important developments in health care in which new information and communication technology developments (including multimedia) play a role and be able to reason on how this might affect the health system.
• Acquire theoretical and practical insight on how to design information and communication technology applications in health care.
• Gain insights into the opportunities and pitfalls of information and communication technology in making health care more effective. Be able to map the main advantages and disadvantages benefits for the different type of stakeholders involved. Understand the basic principles of change management involved for implementing a new technology like ICT in health.
• Learn how to analyse communicative aspects of emerging technologies
related to ICT in health.

Skills:
• Learn how to apply the generic approach of Participatory eHealth Development to develop new ICT based innovations in health.
• Learn how to develop a business case and a business plan for a novel eHealth application and to use software to support the innovation process.
• Learn how to analyse communicative aspects of an emerging technology like ICT in health.
• Acquire skills in the facilitation of group discussions

Inhoud vak
National health systems face great difficulties in providing adequate care for an affordable price. New solutions are being investigated to speed up these processes and to make them more affordable. A promising development is the combined use of hitherto separated sources of information, such as modalities in imaging diagnostics, continuous physiological monitoring, and audio and video monitoring. Each modality presents its own problems, but combined together (multimedia), analysis of all this data can enable fast discoveries in life sciences and lead to novel health care interventions. Another promising field is telemedicine, enabling e.g. the Heart Institute of the Caribbean to build upon the expertise of renowned heart surgeons in Switzerland, at only a marginal cost. Patient empowerment is another major development in health care. Better communication and decision support allow the patient to take responsibility for a part of the care process. These different developments enabled by ICT have an impact on the provision and organization of health care and allow to tailor medicine and health care in general, to the needs of the individual patient.

Incorporating information and communication technology in health care, requires changes in the way of working, new business models and new ways of collaboration. But how do you get these different actors to work together and share their data? How to assist health care professionals in changing over paradigms and business processes? How can we make sure that financial interests do not interfere with patient care? How do we combine all data and ensure privacy? Last, but not least, we discuss the impact of multimedia on communicating scientific findings to different publics. To what extent may the combined use of for example video clips and interactive websites improve the effectiveness of health promotion programs?

In teams of four students, you will study how multimedia applications in health care change expert – patient/user interaction and communication. To this end you will learn how to use different participatory design methodologies in order to develop ICT applications in health care.

Onderwijsvorm
Lectures, assignment, self study

Total contact hours: 54
Lectures: 28
Working groups (staff available)/Training: 26

Toetsvorm
Written exam and group assignment. Both parts need to be passed.
Literatuur


Raad voor de Volksgezondheid, Health 2.0, It's up to you!, Ministry of Health, Welfare and Sport, The Hague, 2010

M. Berg, J.Aarts and J. van der Lei, ICT in Health Care: Sociotechnical Approaches, Methods Inf Med 2003; 42: 297-301

Doelgroep
Course for students within the minor Biomedical and health interventions.

Overige informatie
Guest lecturers:
Drs H. Bakker, Principal Consultant Health Care Cap Gemini
Prof. Dr. P. Kenemans, Gynecology, VU Amsterdam
Dr. J. van der Heijden, Manager Development and Research at Ksyos Telemedical Centre
Drs G.J. Sonneveld, Business Development Manager at Vital Health Software