UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-613	Health Technology Assessment	7.5
Prerequisites	**Department**	**Semester**
None	Life and Health Sciences	3rd
Type of Course	**Field**	**Language of Instruction**
Elective	Pharmacy	English
Level of Course	**Lecturer(s)**	**Year of Study**
2nd Cycle	Panayiotis Petrou	2nd
Mode of Delivery	**Work Placement**	**Co-requisites**
Distance Learning	NA	NA

Course Objectives:

Health Technology Assessment:

Health systems worldwide embrace the same goal: improve health of the population, through efficient finance and delivery of health services.

The transformation of our society has mounted the pressures since higher life expectancy comes at the cost of increased morbidity. Moreover, the advances in technological equipment lead to overdiagnosis, which in many cases are void of clinical significance. This cascades to increased needs, which must be met through constrained financial resources.

In this context, the concept of “health technology assessment” is eminent and it has been defined as “the specialty of assistance to health policymaking”. A comprehensive decision-making context should encompass all aforementioned needs and attributes of the social stakeholders and extenuate their divergent and inconsonant interests, ultimately amalgamating them into a joint strategic framework. It is imperative that the standards of this framework are laid on high grade of evidence data, which, in return, will maximize the utility generated out of health resources. To this end, the assessment of health technologies (HTA) has been established as a pivotal decision-making tool. HTA was introduced as a tool to harness soaring health expenditures, which trailed the unrestrained introduction and reimbursement of new and expensive technology in the 70s and 80s.

An HTA programme, through the use of high quality evidence, assess the short- and long-term consequences, in terms of health and resource use, that stem out of the introduction of a new medical technology. HTA assess medical, organizational, economic and societal impact generated by the use of a technologies within the framework of a health system. This implies that HTA is a multidisciplinary activity which systematically evaluates the effects of a technology

on health, on the availability and distribution of resources and on other aspects of health system performance such as equity and responsiveness.

Along the years, the notion of HTA evolved and currently is positioned at the confluence of pharmaceuticals, medical and surgical interventions.

Therefore, HTA serves as a mediator between research and the world of decision-making (Battista 1996).

The knowledge should not only be transferred but also transformed in order to match the norms of a decision-making process. To this direction, HTA should operate in a systematic and reproducible way. The pillars of HTA adjoined with the corresponding with evidence-based medicine (EBM) and clinical practice guidelines (CPG) and they sum up to a body of best practice initiatives. Their difference is that EBM and CPG are primarily oriented towards clinical and patient level. HTA is oriented towards policy making and can addressed at a specific level of the process. The information varies and may be targeted in investment decision, (procurement of equipment) update of reimbursement formularies, restrictions and pre-approvals pertinent to the use of a products, comparison between alternatives and even disinvestment.

HTA collaborate with decision makers and tailor the activities of the HTA to the needs of the health system. In some case, a horizon scanning is performed in order to proactively act, especially in cases that new products that will incur significant budget impact, are anticipated to enter the market.

Learning Outcomes:

After completion of the course students are expected to be able to:

1. Understand the function of Health as market and identify its flaws
2. Assess value, a highly ambiguous term and differentiate from real value-describe fundamental concepts behind rationing and economic evaluation of health care.
3. Critically analyses the ethical issues policy, principles, methods and analytical techniques appropriate for HTA.
4. Critically discuss the potentials of HTA in health-policy development.
5. Critically discuss the multidisciplinary nature of HTA and the diverse range of skills and knowledge required to conduct the different elements of the process (statistical methods and analysis, outcome measurement, evidence synthesis, health economics, economic evaluation, decision analytic modelling).
6. Efficiently search and glean data for a specific health condition
7. Identify bias in the body of evidence and elaborate research strategies to minimize them
8. Comprehend the context of evidence based medicine from a medical, organizational, patient and policy perspective

9. Understand the fundamentals in economic evaluations of health technologies.
10. Comprehend the necessity for direct and indirect evidence synthesis and the contribution of mixed treatment comparison networks

Course Content:

Health Market overview-The compelling need to regulate it

The health market is a flawed one, a trait which can be primarily attributed to its information asymmetry and its trichotomy attribute between payer, patient and physicians. Their pursuits and interests also deviate; therefore, the decision should satisfy all stakeholders, which will maintain solidarity, equity and social, the pillars of any health system.

What is the notion of evidence in a technology assessment?

Evidence based medicine (EBM) is the conscientious, explicit, judicious and reasonable use of modern, best evidence in making decisions about the care of individual patients. It should be based on rigorous research to the fullest extent possible, in order to avoid bias or even worse, violate the fundamental rights of patients.

Evidence-based medicine has been defined as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett et al. 1996). As stated in the definition, the origin of this evidence-based approach can be seen in the application of clinical medicine delivered at an individual level. “When it is not in our power to follow what is true, we ought to follow what is most probable.”

Systematic observations and research creates evidence, which is inseparable from the notion of data collection. The evidence-based context depends not only on available data but on their thorough, critical and systematic analysis, based on a specific, transparent and reproducible pathway. Therefore, evidence is not just what the name implies but it should be also be practical and useful knowledge.

In the context of EBM, a ranking of the evidence applies, pertinent to the:

• the hierarchy of research designs and;

• the quality of the research.

The study design perpetuates to the quality of the results and the rating of the evidence. Factor such as bias and existence of confounding may augment or compound the outcome, consequently this should also be quantified

Assessment of the research

The validity of the research, on which a HTA is based, is a critical factor which bolsters the hypothesis that the outcome of a study is attributable to the intervention, and not to confounding variables .

The holy grail of evidence is the “randomized controlled trial” (RCT) with size that leads to significant statistical power, thus enabling to identify the effectiveness of an intervention

High internal validity is contingent to the protocol, selection of participants, elimination of selection bias, blinding and selection of meaningful endpoints.

Nevertheless, in real life, there are several impediments towards conducting a sound RCT due to This can happen for a number of reasons:

- Several categories are excluded from trials such as elderly, pregnant and people with comorbidities
- Off-label uses are not assessed.
- Some effects cannot be captured due to duration and size limitations

The way in which an intervention has effects on health is referred to as its

“directness”.

Summarizing research

An HTA program should be able to summarize the -usually -enormous body of evidence into practical points which will facilitate decision makers in reaching an efficient and rational approach contingent to a clinical need

The body of evidence encapsulates several trials and is defined by several characteristics such as the study design, the directness of the evidence and the quality of trial’s execution. In systematic reviews, which feature more than one study other factors intrude such as the number of studies, the heterogeneity/ consistency and the effect size.

Currently, there are over 40 approaches to rate the strength of the evidence while must effort has been devoted in consolidating all this tools into one optimum and less prone to bias, approach.

Apart from rating the strength of evidence, the grade of the recommendation is also instilled in the decision making process. Therefore, is vital to differentiate between the strength of the evidence and the strength of the recommendation, most commonly described as the grade of recommendation.

In the vast majority of the cases, the strength of recommendations is highly pertinent to the strength of evidence and the available tools for grade of recommendations consider the standard, directness, amount and consistency of the evidence, along with the size of the effect

One of the most prominent tools is the GRADE one. The overall quality of the evidence is pertinent to its potential effect by future data. In this sense, High quality evidence is defined as the body of evidence that further research is rather unlikely to change our confidence in the effect estimate and moderate quality evidence is defined as the body of evidence that further research is likely to have an important impact on our confidence in the estimate of effect and may change it. Lastly, low quality evidence is the body of evidence, for which our confidence in the estimate of effect is likely to change in view of further research.

Understanding the design of clinical studies,

The design of clinical studies is of paramount importance in the quest of obtaining solid and high-quality data. A properly designed study which address the potential pitfalls of reporting, attrition, performance and selection bias can offer substantial insight in a product's safety and efficacy profile.

In cases that no properly designed clinical trials exist, the assessment of inferior source of evidence can give us valuable results. Cohort studies offer critical data in the epidemiology of coronary disease and the Framingham Study has been endorsed as the pinnacle of cohort studies. In the vaccine era, metanalysis of cohort studies, the only feasible source of evidence of this-highly prone to misleading and deception-therapeutic area elucidated the impact of vaccines and disentangled its causality with autism.

Battling uncertainty

Uncertainty is a pervasive issue and is ingrained in the health care sector. Intra-and-inter patient variability, limitations of technical equipment and a less-than-optimum understanding of human biology infer that this uncertainty will intrude in the decision-making process. This will deprive patients from utility while it may expose some other patients to unnecessary risk. To this direction, several approaches where elaborated to minimise uncertainty or socialise its burden across the major stakeholders, payers and industry

Evidence synthesis-Systematic reviews and Mixed Treatment comparison

The design of clinical trials is based on regulatory needs and obligations of MaH. This implies that in the majority of the cases, RCT serve a regulatory and not a clinical goal. This concludes that RCT in several cases, do not streamline with clinical needs and concerns.

Systematic reviews and metanalysis display the lowest bias among clinical trials. Nevertheless, their heterogeneity should be scrutinized to rule out significant variation in the included studies.

This gap is filled by new and state-of-the-art data synthesis. The mixed treatment comparison, an innovative platform to create indirect data using existing data, has enabled the comparison of products, whose direct head-to-head trials are clearly out of the context of MaH. Therefore, MTC enables the elaboration of timely, qualitative and policy relevant comparative data.

Health economic modelling

Affordability of health services and the consequent sustainability of health systems escalated to the primary concern of all health systems at a global scale. Decision makers need data with high internal and external validity and this gap can be breached by decision-analytic modelling for economic evaluation of pharmaceutical Synthesis of data through economic modelling has been increasingly utilised by health agencies to provide cost-effectiveness data and facilitate informed decision- making

This confluence of increasing health needs and reduced funds, amid the complex health operational framework, mandates rational selection of medicines in order to maintain sustainability of health system and safeguard unobstructed access of patients to necessary, effective and safe medicines . Accordingly, it is essential to balance multiple policy interests of

the major stakeholders of the pharmaceutical sector that is the Health Agencies, the Industry, physicians and patients. Their strategic goals and pursuits rarely overlap, usually deviate and even conflict since health agencies strive to contain costs, Industry tries to sustain financial prosperity, promote research and development, protect their employment and contribute their positive trade balance, and patients demand timely access to innovative, safe and high-quality medicines.

In light of the above, the application of decision-analytic economic modelling schemes can provide timely approximations with scientific rigour and policy relevance. These can radically contribute to the decision-making process and enhance the maximization of health utility to the society, a doctrine of necessity in current fiscal environment. Modelling serves primarily the following targets

- identification of important factors, among several ones.
- allows combination of data from several sources and evidence synthesis. This will facilitate merging of data from studies with diverse clinical end points and it lead to more robust results and recommendations. The most important data are economic, epidemiological and international data.
- Can create economic data in clinical trials, whose design did not make provision for collecting economic data.
- Can create cost- effectiveness data between actual competitive products, for which no direct clinical data exist.
- Can give answers to long-term health questions.
- Allows representation of the complexity of the real world in a more understandable way.
- Outline and clarify certain areas of uncertainty .
- Enables extrapolation of data from a single study

Learning Activities and Teaching Methods:

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and e-books), access to additional videos and commercials related to the course, synchronous meetings (WebEx), forums, chats, quizzes, case studies and other formative and summative assessments.

Assessment Methods:

Continuous Assessment (assignments), Final Exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
Pharmacoeconomics.	Walley T, Haycox A, Boland A, eds	Churchill Livingstone, Edinburgh.	2004	
Methods for the Economic Evaluation of Health Care Programmes. 2nd edition,	Drummond MF, O'Brien BJ, Stoddart GL, Torrance GW	Oxford University Press, Oxford.	1998	
Introduction to applied pharmacoeconomics.	Vogenburg, FR	McGraw Hill, New York.	2001	