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| Course Title | **Research Methods in Medicine and Essential Medical Statistics** |
| Course Code | **MED-106** |
| Course Type | Required |
| Level | Undergraduate |
| Year / Semester | Year 1/ Semester 2 (Spring) |
| Teacher's Name | **Course Lead:** Dr Constantinos Koshiaris **Contributors:** Prof Avgis Hadjipapas Dr Souzana Achilleos Dr Annalisa Quattrocchi Dr Despo Ierodiakonou Prof Costas Constantinou Prof Zoi Pana |

| ECTS | 6 | Lectures / week | 3 | Laboratories / week | 2 |
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| Course Purpose and Objectives | The move towards Evidence Based Medicine (EBM) on one hand and preventive medicine (Epidemiology and Public Health -PH-) on the other requires some knowledge by medical graduates in terms of Research Methods and Statistics and an ability to understand and critically assess medical research and epidemiological/public health literature. The course will provide the basic building stones for this outcome. Throughout the course medical and epidemiological examples will be used and teaching will always be put in context. Emphasis will be placed on understanding research rationale and research design and on interpreting (rather than calculating) statistics. The overarching objectives of the course are: <br><br> • To understand the principles behind scientific research methods. <br><br> • To understand the rationale behind research in the EBM, epidemiology/PH settings. <br><br> • To cover the basic principles behind the most common study designs used in medical and healthcare research. <br><br> • To introduce basic concepts of summarizing data, descriptive statistics and probability as well as samples and populations. <br><br> • To cover the most common medical statistics such as quantification of risk, measures of association and measures of treatment efficacy. <br><br> At the end of the course students should be able to approach the medical literature systematically and be prepared for acquiring further concepts related to epidemiology, public health and evidence-based medicine in the later years of the course. |

| Learning Outcomes | The following list provides the **learning objectives (LOBs)** that will be covered in the lectures and tutorials of each week: |
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| | **Week 1** |
| | *LOBs covered during lectures:* |
| | 1. Outline the different types of variables in biomedical research. |
| | 2. Determine the applicability of different summary statistics for descriptive analysis of data. |
| | 3. Calculate basic summary statistics, such as mean, median, standard deviation, interquartile range, proportions. |
| | 4. Outline the normal distribution and its statistical qualities and calculate probabilities based on these. |
| | 5. Recognise deviations from normality in a variable distribution and outline skewness. |
| | 6. Describe how skewness and outliers affect measures of central tendency and dispersion and decode which summary statistics are applicable for different types of distributions. |
| | **Week 2** |
| | *LOBs covered during lectures:* |
| | 7. Define and describe disease prevalence, incidence and rates and apply them appropriately for quantifying disease frequency in populations. |
| | 8. Define and describe different types of mortality rates and apply them appropriately for quantifying mortality in populations. |
| | 9. Describe the relationship between incidence, mortality and prevalence. |
| | 10. Define and describe incidence rates and explain its difference from cumulative incidence. |
| | *LOB covered during tutorial:* |
| | 11. Calculate and interpret measures of disease frequency and mortality, such as prevalence, incidence and rates. |
| | **Week 3** |
| | *LOBs covered during lectures:* |
| | 12. Define and interpret the Risk Ratio and the Rate Ratio (Relative Risks) and apply them in relevant research scenarios. |
| | 13. Define and interpret the Odds Ratio and apply it in relevant research scenarios. |

*LOBs covered during tutorial:*

14. Calculate, interpret and appropriately apply Risk Ratios and Rate Ratios for morbidity and mortality data.

15. Calculate, interpret and appropriately apply Odds Ratios morbidity and mortality data.

## Week 4

*LOBs covered during lectures:*

16. Identify and apply measures of association for numeric outcomes and categorical exposures.

17. Interpret the mean difference between groups.

18. Name the different statistical techniques (tests) used for assessing associations between categorical exposures and numeric outcomes.

19. Interpret the correlation coefficient and the regression coefficient. Name the different statistical techniques (tests) used for assessing associations between categorical exposures and numeric outcomes.

*LOB covered during tutorial:*

20. Interpret and appropriately apply basic measures of association, such as the mean difference, correlation coefficient and regression coefficient.

## Week 5

*LOBs covered during lectures:*

21. Describe the concept of the sample and how it relates to the population.

22. Describe the concept of the estimate and its importance in medical research.

23. Describe the concept of the random error (chance).

24. Formulate the null and alternative hypothesis for given research scenarios.

## Week 6

*LOBs covered during lectures:*

25. Describe the statistical principles of hypothesis testing.

26. Interpret a p-value and use it to infer statistical significance.

27. Interpret a 95% Confidence Interval and use it to infer statistical significance.

28. Describe Type I and Type II errors and how these may arise.

*LOBs covered during tutorials:*

29. Evaluate the presence of associations in published research based on the p-value and the 95% Confidence Interval.
30. Detect Type I and Type II errors.

## Week 7

## Midterm examination

*LOBs covered during lectures:*

31. Differentiate between random error and systematic error.
32. Outline the different sampling methods and describe how each of these can give rise to selection bias.
33. Describe selection bias and how it affects the validity of research studies.
34. Outline the different types of information bias.
35. Describe how information bias affects the validity of research studies.
36. Differentiate between the concepts of validity and reliability.
37. Describe the major types of validity and reliability.

*LOBs covered during tutorials:*

38. Identify the sampling method in published research studies.
39. Evaluate the presence of selection bias in published research studies.
40. Evaluate the presence of information bias in published research studies.
41. Evaluate the validity and reliability of different assessment tools.

## Week 8
*LOBs covered during lectures:*

42. Recognize the multifactorial nature of health and disease.
43. Describe the concept of the confounder.
44. Describe the presence of potential confounding in different research scenarios.
45. Differentiate between crude and adjusted estimates.
46. Describe the concept of the 'independent' risk factor.

47. Differentiate between a confounder and a mediator.

48. Describe the concept of residual confounding and over adjustment.

*LOBs covered during tutorial:*

49. Evaluate the presence of confounding in published research studies.

50. Interpret confounder-adjusted estimates.

## Week 9

*LOBs covered during lectures:*

51. Differentiate between internal and external validity.

52. Describe the main concepts of internal and external validity.

53. Judge on internal and external study validity in published research studies.

54. Describe the different study designs in observational research (cross-sectional, case-control, cohort).

55. Describe the strengths and limitations of observational research.

## Week 10

*LOBs covered during lectures:*

56. Describe the different study designs in interventional research (randomized controlled trials and other clinical trial designs).

57. Describe the strengths and limitations of interventional research.

58. Describe the different levels of evidence.

*LOBs covered during tutorial:*

59. Recognise the different study designs in published research studies.

60. Decide the appropriate study design for addressing specific research questions.

61. Identify the level of evidence for specific research scenarios in the literature.

## Week 11

*LOBs covered during lectures:*

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| | 62. Differentiate between the concepts of association and causation.<br><br>63. Describe the main criteria that help in inferring a causal relationship.<br><br>64. Describe necessary and sufficient causes.<br><br>***LOBs covered during tutorials:***<br><br>65. Judge on causality in published research studies.<br><br>**Week 12**<br>***LOBs covered during lectures:***<br><br>66. Define qualitative research.<br><br>67. Describe the various qualitative research methodologies.<br><br>68. Describe the process of coding qualitative data.<br><br>69. Describe the process of analysing qualitative data.<br><br>***LOB covered during tutorial:***<br><br>70. Apply the basic qualitative methodology to analyse a specific case. | | | |
| Prerequisites | None | Required | None |
| Course Content | ***Lecture Topics:***<br><br>• Introduction to Biomedical Research<br><br>• Introduction to measurement I: types of variables and basic summary statistics.<br><br>• Introduction to measurement II: frequency distributions and the normal distribution.<br><br>• Measures of frequency I: proportional measures<br><br>• Measures of frequency II: rates<br><br>• Measures of association I: The Risk Ratio and the Rate Ratio (Relative Risks).<br><br>• Measures of association II: The Odds Ratio.<br><br>• Measures of association III: mean difference between groups.<br><br>• Measures of association IV: association of two numeric variables (correlation and linear regression).<br><br>• Introduction to sampling and statistical inference I: samples, populations and the random error.<br><br>• Introduction to sampling and statistical inference II: hypothesis testing and statistical significance (the 95% confidence interval and the p-value). | | |

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<ul>
<li>Systematic error in research I: selection bias and the different sampling methods.</li>
<li>Systematic error in research II: information bias (measurement error).</li>
<li>Introduction to confounding I: the multifactorial nature of disease and the concept of the confounder.</li>
<li>Introduction to confounding II: dealing with confounding (identifying 'independent' risk factors).</li>
<li>Causality in medical research: association vs causation.</li>
<li>Internal and external study validity.</li>
<li>Types of study design I: Observational studies.</li>
<li>Types of study design II: Interventional studies.</li>
<li>The level of evidence in medical research.</li>
<li>Introduction to Qualitative research methods.</li>
<li>Introduction to Qualitative analysis</li>
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***Tutorial Topics:***
<ul>
<li>Calculating and reporting prevalence, incidence and rates.</li>
<li>Calculating and reporting Relative Risks and Odds Ratios.</li>
<li>Interpreting measures of associations with numeric outcomes.</li>
<li>Identifying associations and judging on statistical significance.</li>
<li>Judging on the presence of selection bias and information bias.</li>
<li>Judging on causality and validity.</li>
<li>Judging on confounding in associations.</li>
<li>Judging on the type of study design and the level of evidence.</li>
<li>Basic analysis of qualitative data.</li>
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| Teaching Methodology | Lectures, Tutorials. |
| Bibliography | **Required Textbooks/Reading:** |

| Authors | Title | Edition | Publisher | Year | ISBN |
|---|---|---|---|---|---|
| Petrie A., Sabin C. | Medical statistics at a glance. | 4th Edition | Wiley-Blackwell | 2019 | 978111 9167815 |

**Recommended Textbooks/Reading:**

| Authors | Title | | Publisher | Year | ISBN |
|---|---|---|---|---|---|

| | Charles H. Hennekens | Epidemiology in Medicine, Volume 515 | Lippincott Williams & Wilkins | 1987 | 0316356360, 9780316356 367 | |
| | Hurley, W.L. et al. | Research methods: A Framework for Evidence-Based Clinical Practice | LWW | 2011 | 978078179 7689 | |
| | Babu, Ajit N. | Clinical research Methodology and Evidence based Medicine: the basics | Anshan Limited UK | 2008 | 978190574 0901 | |
| | Kathryn Jacobsen | Introduction to Health Research Methods | Jones & Bartlett Publishers 3rd Edition | 2020 | 97812841 97563 | |
| Assessment | Coursework (10%), Midterm Exam (30%), and Final Exam (60%). Assessment is by Single Best Answers (SBAs) and Short Answer Questions (SAQs). | | | | | |
| Language | English | | | | | |