

# Research Summary

## TIPS:

- **99% ENOUGH FOR FULL MARK BUT YOU ARE RECOMMENDED TO WATCH THE LECTURE RECORDS PARTICULARLY THE PRACTICAL LECTURES**
  - **The red once “ has been asked in Gifts”**
  - **The red and highlighted red “Are mentioned by doctors + in the Gift”**
- everything in the slides has been added in this summary so you can relay in the summary alone
- Focus on everything has red color ‘-‘

## Editing file



Black: in male AND female slides  
Red : important  
Gray: extra information



# 15 lectures :

Research questions, objectives and hypotheses

Ethics in health research

How to do Literature Search?

Measures of Disease Frequency, Effect & Impact

Practical Session: Measuring Risk, Incidence & Prevalence

Practical Session: Odds Ratio & Minimizing Bias

Practical Session: Relative Risk, Confounding

Introduction to Study Designs

Cross Sectional Study Design

Case Control study Design

Cohort Study Design

Experimental Study Design

Qualitative Study Designs

Practical Session: Selection of Study Design

Tools for data collection: Using Questionnaire & other tools



# L1 Research questions, objectives and hypotheses

<b>Research question</b>	<p>Uncertainty(not sure-no evident)about the something in the population that the investigator wants to resolve by measurements in the population.</p> <p>Uncertainty = data needs</p>
<b>Clear research question facilitates:</b>	<ul style="list-style-type: none"> <li>• Choosing the <b>optimal study design(Q)</b></li> <li>• Identify <b>who</b> should be included, <b>what</b> outcomes to measure and <b>when</b> to measure</li> </ul>
<b>Translating Uncertainty to Research Questions</b>	<ul style="list-style-type: none"> <li>- Frames problem in specific terms (clinical / public health / ... etc..)</li> <li>- Focuses on one issue.</li> <li>- Written in everyday language.</li> <li>- Links to a potential action once the question is answered.</li> <li>- <b>Is stated as a question</b></li> </ul>

Sources for Research questions	Categories of Research Question(Q) <small>Dr.note : they might give you a Question and ask if it Descriptive or Analytical</small>	Steps in conceiving a research question
<ol style="list-style-type: none"> <li>1. Literature Review.</li> <li>2. New ideas, technologies and innovation.</li> <li>3. Careful observation.</li> <li>4. Mentors / Guides.</li> </ol>	<ol style="list-style-type: none"> <li>1. <b>Descriptive Questions</b> : <ul style="list-style-type: none"> <li>- observations to measure <u>quantity</u> and <b>NO comparison group</b> / intervention</li> </ul> </li> <li>2. <b>Analytical Questions</b>: <ul style="list-style-type: none"> <li>- <b>involve comparisons</b> / interventions <u>to test hypothesis</u></li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. <b>Review</b> of up to date literature and information.</li> <li>2. Raise a question.</li> <li>3. Decide worth investigating by <b>peer-review</b>.</li> <li>4. <b>Define</b> measurable exposures and outcomes.</li> <li>5. Sharpen the initial question.</li> <li>6. Refine the question by specifying details (<b>PICOT!</b>)</li> </ol>

<b>PICOT Criteria(Q)</b>
<ol style="list-style-type: none"> <li>1. <b>P</b>opulation / <b>P</b>atients “Who are the relevant patients? Think about age, sex, geographic location, or specific characteristics that would be important to your question”.</li> <li>2. <b>I</b>ntervention / <b>I</b>ndicator “What is the treatment, diagnostic test, or exposure that you are interested in? <ul style="list-style-type: none"> <li>- What is the difference between intervention and indicator? Indicators are things that are already present in the person e.g. Sex, Age, Smoking (You can’t do harmful interventions like making someone smoke)</li> </ul> </li> <li>3. <b>C</b>omparison/<b>C</b>ontrol “Is there a control or alternative treatment you would like to compare to the intervention or indicator?”</li> <li>4. <b>O</b>utcome “What do you intend to accomplish, measure, improve or affect?”</li> <li>5. <b>T</b>ime “What is the appropriate follow-up time to assess outcome?”</li> </ol>

<b>Then Passing the “So What?!” Test: FINER (Q)</b>
<ol style="list-style-type: none"> <li>1. <b>F</b>easible “• Adequate number of subjects • Adequate technical expertise • Affordable in time and money • Manageable in scope”</li> <li>2. <b>I</b>nteresting “Getting the answer intrigues investigator, peers and community”</li> <li>3. <b>N</b>ovel “Confirms, refutes or extends previous findings”</li> <li>4. <b>E</b>thical “Amenable to a study that institutional review board will approve”.</li> <li>5. <b>R</b>elevant “• To scientific knowledge • To clinical and health policy • To future research”</li> </ol>

<b>Hypothesis</b>	<ul style="list-style-type: none"> <li>- is a specific and measurable version of the research question.</li> <li>- <b>Hypotheses are only for Analytical Questions (Comparisons)(Q)</b> while purely Descriptive Questions: No</li> </ul>
-------------------	---

<b>Why Hypothesis is important ?</b>	<ol style="list-style-type: none"> <li>1. Summarizes the 3 main elements of the study: <b>sample, exposure and outcome</b>.</li> <li>2. Establishes the basis for the statistical tests of significance.</li> </ol>
--------------------------------------	---

<b>Characteristic of good hypothesis :</b>	<ol style="list-style-type: none"> <li>1. Simple: one exposure and one outcome</li> <li>2. Specific : clear study participants and variable</li> <li>3. Stated in advance : written at the start of the study and focused on 1ry objective</li> </ol>
--	---

<b>Objectives</b>	<ul style="list-style-type: none"> <li>- <b>Objective</b>: an active statement about how the study is going to answer the specific research question. We use no more than one verb for each objective and we should state primary and secondary objectives.</li> <li>- <b>Objectives are important for two reasons</b>: <ol style="list-style-type: none"> <li>1. For the development of the <b>protocol and design of study</b>.</li> <li>2. For the <b>sample size calculations</b> and <b>determining the power of the study</b>.</li> </ol> </li> </ul> <p>Contrary to hypotheses, <b>both descriptive and analytical questions require objectives</b>.</p>
-------------------	---

### Descriptive studies:

1) Estimating a quantity 2) Use the verb “Estimate” e.g.: To estimate the prevalence of vaping among medical students.

### Analytical Studies:

1) Testing a hypothesis 2) Use the verb “Determine” e.g. To determine whether vaping increases the chance of smoking abstinence.

# L2 Ethics in health research

<b>Definition of research</b>	<ul style="list-style-type: none"> <li>A class of activities designed to develop or contribute to generalizable knowledge.</li> <li>a careful and detailed study into a specific problem, concern, or issue using the scientific</li> </ul>						
<b>Practice</b> <small>Dr said: imp to differentiate between research and practice</small>	<ul style="list-style-type: none"> <li>A class of activities designed solely to enhance the wellbeing of individual patient. Diagnosis, preventive treatment or therapy</li> </ul>						
<b>Classes of research</b>	<table border="0"> <tr> <td>1) Experimental or Non experimental</td> <td>3) Basic or Applied</td> </tr> <tr> <td>2) Quantitative or Qualitative</td> <td>4) Therapeutic or Non therapeutic</td> </tr> </table>	1) Experimental or Non experimental	3) Basic or Applied	2) Quantitative or Qualitative	4) Therapeutic or Non therapeutic		
1) Experimental or Non experimental	3) Basic or Applied						
2) Quantitative or Qualitative	4) Therapeutic or Non therapeutic						
<b>Importance of ethics in research</b>	<ul style="list-style-type: none"> <li><b>Protection of participants</b> protect the violation of the rights of study participants</li> <li>Safeguard against exploitation</li> <li>Ensure good clinical practice in research</li> <li>Ensure respect of individuals, dignity, confidentiality, and privacy</li> <li>Safeguard against violations in research and research misconduct</li> </ul>						
<b>NUREMBERGE CODE</b>	INFORMED CONSENT , QUALIFIED RESEARCHER , APPROPRIATE RESEARCH DESIGN , FAVORABLE RISK/BENEFIT RATIO , PARTICIPANT FREEDOM TO STOP						
<b>General islamic principles relating to research</b>	<table border="0"> <tr> <td> <ul style="list-style-type: none"> <li>Devotional purposes &amp; purposes of law</li> <li>Preventing &amp; elimination of haram</li> <li>Observing moral principles &amp; virtues</li> <li>Good treatment/dealing with people</li> </ul> </td> <td> <ul style="list-style-type: none"> <li>Best interest</li> <li>Consequences</li> <li>Protecting rights</li> <li>Duty of care &amp; caring</li> </ul> </td> <td> <ul style="list-style-type: none"> <li>Observing fiqh principles</li> </ul> </td> </tr> </table>	<ul style="list-style-type: none"> <li>Devotional purposes &amp; purposes of law</li> <li>Preventing &amp; elimination of haram</li> <li>Observing moral principles &amp; virtues</li> <li>Good treatment/dealing with people</li> </ul>	<ul style="list-style-type: none"> <li>Best interest</li> <li>Consequences</li> <li>Protecting rights</li> <li>Duty of care &amp; caring</li> </ul>	<ul style="list-style-type: none"> <li>Observing fiqh principles</li> </ul>			
<ul style="list-style-type: none"> <li>Devotional purposes &amp; purposes of law</li> <li>Preventing &amp; elimination of haram</li> <li>Observing moral principles &amp; virtues</li> <li>Good treatment/dealing with people</li> </ul>	<ul style="list-style-type: none"> <li>Best interest</li> <li>Consequences</li> <li>Protecting rights</li> <li>Duty of care &amp; caring</li> </ul>	<ul style="list-style-type: none"> <li>Observing fiqh principles</li> </ul>					
<b>Major principles of research in Islam</b>	<p><b>Two major principles:</b> The accrue of benefits جلب المصالح <u>and</u> the warding off of harm المفساد درا</p> <p><b>Five grand principles:</b></p> <table border="0"> <tr> <td>1. Intent in all-important action الأمور بمقاصدها</td> <td>4. Harm should be removed لا ضرر ولا ضرار</td> </tr> <tr> <td>2. Hardship endangers facilitation المشقة تجلب التيسير</td> <td>5. Custom is true العادة محكمة</td> </tr> <tr> <td>3. Certainty cannot be removed by doubt اليقين يزول بالشك</td> <td></td> </tr> </table>	1. Intent in all-important action الأمور بمقاصدها	4. Harm should be removed لا ضرر ولا ضرار	2. Hardship endangers facilitation المشقة تجلب التيسير	5. Custom is true العادة محكمة	3. Certainty cannot be removed by doubt اليقين يزول بالشك	
1. Intent in all-important action الأمور بمقاصدها	4. Harm should be removed لا ضرر ولا ضرار						
2. Hardship endangers facilitation المشقة تجلب التيسير	5. Custom is true العادة محكمة						
3. Certainty cannot be removed by doubt اليقين يزول بالشك							

## Ethical requirements

<b>Scientific value</b>	Responsible use of finite resources, Avoidance of exploitation, Not to expose human being to potential harms without some possible social or scientific benefit, prioritization .																		
<b>Scientific validity</b> <small>استخدام طرق سليمة وعلمية</small>	Use accepted scientific principles and methods to produce reliable and valid data.																		
<b>Fair subject selection</b>	Selection of subjects so that stigmatized and vulnerable individuals are not targeted for risky research. <b>Justice</b>																		
<b>Favourable risk benefit ratio</b>	<ul style="list-style-type: none"> <li>Minimizing risk and Enhancement of potential benefits.</li> <li><b>“Non-Maleficence, Beneficence”</b></li> </ul> <p style="text-align: right;"><small>When the researcher fails to state the participants about the risk : he missed one of the ethical principle ( <b>Beneficence</b> )</small></p>																		
<b>Respect for subjects</b>	<table border="0"> <tr> <td> <ul style="list-style-type: none"> <li>Protecting privacy</li> <li>New risks or benefits</li> <li><b>Autonomy &amp; Right</b></li> </ul> </td> <td> <ul style="list-style-type: none"> <li>Results of clinical research</li> <li>Maintain welfare of subjects</li> </ul> </td> </tr> </table>	<ul style="list-style-type: none"> <li>Protecting privacy</li> <li>New risks or benefits</li> <li><b>Autonomy &amp; Right</b></li> </ul>	<ul style="list-style-type: none"> <li>Results of clinical research</li> <li>Maintain welfare of subjects</li> </ul>																
<ul style="list-style-type: none"> <li>Protecting privacy</li> <li>New risks or benefits</li> <li><b>Autonomy &amp; Right</b></li> </ul>	<ul style="list-style-type: none"> <li>Results of clinical research</li> <li>Maintain welfare of subjects</li> </ul>																		
<b>Informed consent</b> <small>Informed consent is consent given by a competent individual who received the necessary information, who has adequately understood the information, and who after considering the information, has arrived at a decision without been subject to coercion, undue influence or inducement or intimidation.</small>	<ul style="list-style-type: none"> <li>Is a process by which an individual voluntarily expresses his or her willingness to participate in a particular study after having been informed of all aspects of study that are relevant to the decision to participate.</li> <li>Give information/Understanding and Comprehension of info./Consent and voluntariness</li> <li>Conditions: Right - Cognizance - Capacity - Voluntariness - Lawful Procedure</li> </ul> <table border="0"> <tr> <td><b>Conditions Of informed consent:</b></td> <td>3. Capacity العقل والبلوغ وهما اثنان بوجود اثنان</td> </tr> <tr> <td>1. Right صادر من له الحق</td> <td>4. Voluntariness الاختيار وعدم الاكراه</td> </tr> <tr> <td>2. Lawful procedure أن يكون مأذون بها شرعاً</td> <td>5. Cognizance يعطي الإذن على بينة وادراك (البصيرة)</td> </tr> </table> <table border="0"> <tr> <td><b>Essential elements of informed consent:</b></td> <td>- A statement that the study involves research.</td> </tr> <tr> <td>- A description of any reasonably foreseeable risks or discomforts to the subject.</td> <td>- <b>Assurance of confidentiality.</b></td> </tr> <tr> <td>- A description of any expected benefits to the subject or to others.</td> <td>- A statement about compensation.</td> </tr> <tr> <td>- A disclosure of appropriate alternative procedures or courses of treatment..</td> <td>- Contact details.</td> </tr> <tr> <td></td> <td>- Assurance of voluntariness of participation.</td> </tr> <tr> <td></td> <td>- <b>Statement of protecting participants privacy</b></td> </tr> </table> <p><b>ADDITIONAL ELEMENTS:</b> Unforeseeable risks , Termination of participation, Additional costs , Consequences of withdrawal , Significant new findings , Number of participants</p>	<b>Conditions Of informed consent:</b>	3. Capacity العقل والبلوغ وهما اثنان بوجود اثنان	1. Right صادر من له الحق	4. Voluntariness الاختيار وعدم الاكراه	2. Lawful procedure أن يكون مأذون بها شرعاً	5. Cognizance يعطي الإذن على بينة وادراك (البصيرة)	<b>Essential elements of informed consent:</b>	- A statement that the study involves research.	- A description of any reasonably foreseeable risks or discomforts to the subject.	- <b>Assurance of confidentiality.</b>	- A description of any expected benefits to the subject or to others.	- A statement about compensation.	- A disclosure of appropriate alternative procedures or courses of treatment..	- Contact details.		- Assurance of voluntariness of participation.		- <b>Statement of protecting participants privacy</b>
<b>Conditions Of informed consent:</b>	3. Capacity العقل والبلوغ وهما اثنان بوجود اثنان																		
1. Right صادر من له الحق	4. Voluntariness الاختيار وعدم الاكراه																		
2. Lawful procedure أن يكون مأذون بها شرعاً	5. Cognizance يعطي الإذن على بينة وادراك (البصيرة)																		
<b>Essential elements of informed consent:</b>	- A statement that the study involves research.																		
- A description of any reasonably foreseeable risks or discomforts to the subject.	- <b>Assurance of confidentiality.</b>																		
- A description of any expected benefits to the subject or to others.	- A statement about compensation.																		
- A disclosure of appropriate alternative procedures or courses of treatment..	- Contact details.																		
	- Assurance of voluntariness of participation.																		
	- <b>Statement of protecting participants privacy</b>																		

# L2 Ethics in health research

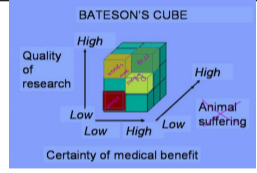
## Ethical requirements

<p><b>Informed consent</b></p>	<p><b>IC READIBILITY :</b>          LANGUAGE: :LANGUAGE OF PARTICIPANTS ,EXPLANATION/ INTERPRETATION ,SIMPLE LANGUAGE          LEGIBILITY          AVOID MEDICAL JARGON</p> <p><b>Waiver of informed consent:</b></p> <ul style="list-style-type: none"> <li>- Minimal risk.</li> <li>- Rights and welfare of participants protected.</li> <li>- Research not possible without a waiver.</li> <li>- Appropriate information provided</li> </ul>
<p><b>Observance of sharia and law</b></p>	<p>INDEPENDENT REVIEW :</p> <ul style="list-style-type: none"> <li>● Proposed subject population</li> <li>● Review design</li> <li>● Risk – Benefit Ratio</li> <li>● “Conflict of interest”</li> </ul>

**Observance of the local laws/policies**

**Bateson’s cube:** evaluates proposed research through three criteria:

- 1) The degree of animal suffering.
- 2) The quality of research.
- 3) The potential medical benefit.



## THE RESEARCHER VIRTUES

- SINCERITY/FAITHFULNESS
  - OBSERVANCE OF ALLAH
  - INTEGRITY/HONESTY :
1. ORIGINALITY OF THE STUDY
  2. REVIEW OF PREVIOUS STUDIES
  3. TRUTHFULNESS ABOUT THE BENEFITS & RISKS
  4. SCIENTIFIC CAPABILITY
  5. SCIENTIFIC INTEGRITY
  6. IMPARTIALITY
  7. APPROPRIATE RESEARCH TEAM
  8. OBSERVING RIGHTS OF COLLABORATORS

# L3 How to do Literature Search?

<b>Why Searching a literature?</b>	<ul style="list-style-type: none"> <li>- <u>Staying</u>: Staying current with advances in medicine</li> <li>- <u>Identifying</u>: Identifying information and ideas , seminal works in your area</li> <li>- <u>Increasing</u>: Increasing your breadth of knowledge</li> <li>- <u>Carrying</u>: Carrying on from where others have already reached</li> <li>- <u>Avoiding</u>: Avoiding reinventing the wheel</li> <li>- <u>Putting</u>: Putting your work into perspective</li> </ul>			
<b>5-step EBM process</b>	<p>Start by assessing the impact of change then ask clinical question then acquire available resources then appraise(قيم)quality then apply it by practicing .</p>			
<b>Clinical question:</b>	<b>Background questions</b>	<b>Foreground questions</b>		
	Very basic and broad questions, usually asked by novices.From books.ex:“What is malaria?”.	After specifying and limiting the background question, usually asked by experts ex:Are bed nets effective in lowering the incidence/prevalence of malaria in developing countries?.		
<b>Where do you search for evidence?</b>	<table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top;"> <ul style="list-style-type: none"> <li>● <b>ACP Clinical Guidelines and Recommendations</b></li> <li>● <b>BMJ BestPractice/Clinical Evidence</b></li> <li>● <b>ClinicalKey/MDConsult</b></li> <li>● <b>Cochrane Library</b></li> <li>● <b>DynaMed</b></li> <li>● <b>Essential Evidence Plus</b></li> <li>● <b>Google</b></li> <li>● <b>Google Scholar</b></li> <li>● <b>Medscape</b></li> </ul> </td> <td style="vertical-align: top;"> <ul style="list-style-type: none"> <li>● PubMed</li> <li>● <b>Saudi Digital Library</b></li> <li>● Skyscape</li> <li>● StatRef</li> <li>● TRIP Database</li> <li>● UpToDate</li> <li>● Web of Knowledge</li> <li>● WebMD (Med-U)</li> <li>● Other</li> </ul> </td> </tr> </table>		<ul style="list-style-type: none"> <li>● <b>ACP Clinical Guidelines and Recommendations</b></li> <li>● <b>BMJ BestPractice/Clinical Evidence</b></li> <li>● <b>ClinicalKey/MDConsult</b></li> <li>● <b>Cochrane Library</b></li> <li>● <b>DynaMed</b></li> <li>● <b>Essential Evidence Plus</b></li> <li>● <b>Google</b></li> <li>● <b>Google Scholar</b></li> <li>● <b>Medscape</b></li> </ul>	<ul style="list-style-type: none"> <li>● PubMed</li> <li>● <b>Saudi Digital Library</b></li> <li>● Skyscape</li> <li>● StatRef</li> <li>● TRIP Database</li> <li>● UpToDate</li> <li>● Web of Knowledge</li> <li>● WebMD (Med-U)</li> <li>● Other</li> </ul>
<ul style="list-style-type: none"> <li>● <b>ACP Clinical Guidelines and Recommendations</b></li> <li>● <b>BMJ BestPractice/Clinical Evidence</b></li> <li>● <b>ClinicalKey/MDConsult</b></li> <li>● <b>Cochrane Library</b></li> <li>● <b>DynaMed</b></li> <li>● <b>Essential Evidence Plus</b></li> <li>● <b>Google</b></li> <li>● <b>Google Scholar</b></li> <li>● <b>Medscape</b></li> </ul>	<ul style="list-style-type: none"> <li>● PubMed</li> <li>● <b>Saudi Digital Library</b></li> <li>● Skyscape</li> <li>● StatRef</li> <li>● TRIP Database</li> <li>● UpToDate</li> <li>● Web of Knowledge</li> <li>● WebMD (Med-U)</li> <li>● Other</li> </ul>			
(Note's <sup>1</sup> dc next page )Haynes' 5S pyramid of EBM resources:				
<b>Systems</b>	clinical decision support system (CDS) <b>Examples:</b> HER built-in CDSs, Diagnosis One, AHRQ ePSS			
<b>Summaries</b>	Evidence based CPG -Evidence based textbooks <b>Examples:</b> BMJ BestPractice, BMJ ClinicalEvidence, UptoDate, StatRef.			
<b>Synopses</b>	Evidence based journal abstracts- <b>Examples:</b> DynaMed, PIER, EE+			
<b>Syntheses</b>	Systematic reviews - Example: Cochrane library, Trip Database <b>What is Systematic Reviews and Meta-analysis?</b> - <b>Systematic Review of Studies:</b> is a thorough, comprehensive, and explicit interrogation of the medical literature. - <b>Meta-analysis:</b> is a statistical approach to combine the data derived from			
<b>Studies</b>	Original journals - <b>Examples:</b> Medline mobile			
Archie Cochrane (1909-88)				
Made by Archie Cochrane (1909-88) <ul style="list-style-type: none"> <li>- British epidemiologist</li> <li>- Advocated RCTs to inform healthcare practice</li> </ul>	Cochrane collaboration: <ul style="list-style-type: none"> <li>- Cochrane Reviews (&gt;4,000) registered</li> <li>- Identify, appraise and synthesize research-based evidence and present it in accessible format; regularly updated</li> <li>- Focus on interventions</li> <li>- Outstanding general resource</li> </ul>			
<b>Primary Resources:</b>	Global databases: • (Cochrane, PubMed, HealthPubMed, Ovid, Science Citations, grey literature, etc.) WHO databases • (global/regional): observatories; scientific journals (WHO Bulletin/EMHJ); surveillance; surveys; ICTRP; CPG, etc. National databases: • ENSTINET, SaudiMedLit; NCHS, CAPMAS; healthcare delivery institutions (websites, reports); clinical trials; grey literature, etc.			
<b>PubMed</b>	<ul style="list-style-type: none"> <li>- is a database developed by the National Center for Biotechnology Information (NCBI) at the U.S. National Library of Medicine (NLM) available on the Web.</li> <li>- is more current and comprehensive than MEDLINE it includes citations even prior to their indexing with MEDLINE)</li> <li>- provides access to MEDLINE</li> <li>- provides information for consumers and clinicians on prevention and treatment of diseases and conditions.</li> <li>- specializes in reviews of clinical effectiveness research, with easy-to-read summaries for consumers as well as full technical reports. Clinical effectiveness research finds answers to the question “What works?” in medical and health care.</li> </ul> Source :MEDLINE (NLM database) , Life science journals , Online books - For all fields .			

# L3 How to do Literature Search?

<b>Where to start?</b> 1st step in doing literature: identify key words that w'll be used	<b>General overview:</b> <ul style="list-style-type: none"> <li>• Internet search/Any search engine</li> <li>• Guidelines review</li> </ul>	<b>Thorough search</b> Database search – Medline/PsycINFO <ul style="list-style-type: none"> <li>• Reference tracking-references in articles</li> </ul>	<b>Refining</b> Expert contacts
--	---	--	------------------------------------

## More thorough search?

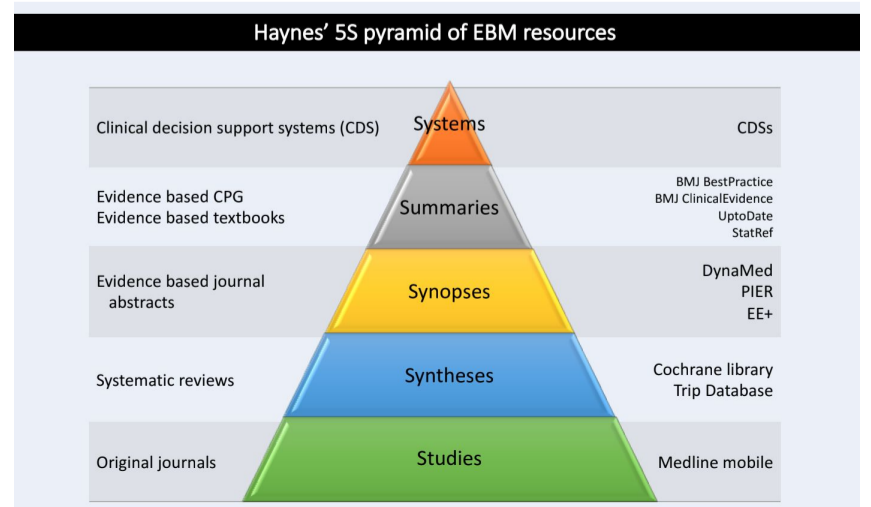
- Prepare :Make a list of all the terms connected with our topic.
- Organize :Make a list of the words that are critical to your search-Exchange/add words if needed-Note terms that you don't want to appear - Discard the rest.
- **Combine : Use Boolean operators** to combine our most important terms ( **And** for connections of terms , **or** for similar terms , **not** for excluding

MeSH indexing	Keys to Successful Searching	Critical Appraisal Table – Key Elements
<ul style="list-style-type: none"> <li>• Acronym for “Medical Subject Headings”</li> <li>• Similar to key words on other systems</li> <li>• Used for indexing journal articles for MEDLINE</li> <li>• Arranged in hierarchy, from more general to more specific</li> <li>• Used by researchers</li> </ul> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>This will help you exclude all other diseases in that category</b></li> <li><input type="checkbox"/> <b>This will give you fewer articles in your results page</b></li> </ul>	<b>Indexes:</b> Identifying appropriate indexes through clinical questions <b>Components of “well-built clinical questions.”: PICOT</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Reference or ID number</li> <li><input type="checkbox"/> Study Design</li> <li><input type="checkbox"/> Participants</li> <li><input type="checkbox"/> Characteristics of the problem within the population</li> <li><input type="checkbox"/> Intervention outcomes.</li> <li><input type="checkbox"/> Include or exclude the study?</li> </ul>

<b>Key Elements of High Quality Articles</b>	<p>article meets standards for publication. The criteria includes: quality, significance, methodology, and importance.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>Currency</b> Locating the most current five or ten years of information is not a gold standard. There are several factors that determine how far back in time your search should run.</li> <li><input type="checkbox"/> <b>Clearly <u>recognized research question or problem</u>:</b> The introduction or background should include what is known, what is unknown and what is the author's aim or hypothesis.</li> <li><input type="checkbox"/> <b>Study design</b> Revisit the <u>PUBLIC HEALTH EVIDENCE BASED PYRAMID</u> to review different types of study designs.</li> <li><input type="checkbox"/> <b>Times Cited</b> This is an indication that something important is going on with the article, but one should not assume that the article is necessarily good</li> </ul>
--	---

<b>Summarizing the Literature Review :</b>	<p><b>Introduction:</b> Gives a quick idea of the topic of the literature review, such as the central theme or organizational pattern.</p> <p><b>Body:</b> Contains your discussion of sources and is organized either <b>chronologically, thematically, or methodologically</b></p> <p><b>Conclusions/Recommendations:</b> Discuss what you have drawn from reviewing literature so far. Where might the discussion proceed?</p>
--	---

1-(studies ) - if you want to search for reviews, topics is not the best way (why?) because it's abroad and not all has evidence based and you need to find many researches has Background question. ( syntheses) - result from many studies in one document ex systemic review . ( synapses ) - findings of the synthesis. The most important ( summaries) -combined results of the synapses and the experts opinion to create single document that can provide recommendations ( som important for decision maker . ( Systems) - CDS these electronic information will link the information with guidelines for practice to create the best Heath care practice.



# L4 Measures of Disease Frequency, Effect & Impact

<b>Measures For Disease Frequency</b>	<b>Prevalence:</b> The amount of a disease in a population at a given point in time Know how to calculate the prevalence it's important "what's the prevalence of..?" chick the practical for this lec	<b>Period Prevalence:</b> The proportion of the population that has the disease during a specified period of time Period prevalence = Number of current cases during a specific period of time / Average or mid-interval population(Q)	<b>Point Prevalence:</b> The proportion of the population that has the disease at a specific point in time Point Prevalence = Number of current cases at a specific point in time / Total population at that same point in time	
	<b>Incidence Proportion:</b> The population at risk is a well-defined population that is free of the disease at the beginning of the study and has certain characteristics that put them at risk for developing the disease. Incidence Proportion = Number of new cases / total population at risk at the beginning of the study	<b>Incidence Rate:</b> Here we are taking into consideration the time that each person spent being at risk before developing the disease. By contrast the incidence proportion only considers the total population at risk without also incorporating time in the equation. Incidence Rate = Number of new cases / the total person time at risk over the study period of time		
	you have to differentiate between them very well if we say: A study followed 3,000 males ages 45 years and older for 5 years to assess the development of MI. During the study period, 150 men developed MI, who accumulated a total person-time of 14,625 person-years. What is the incidence proportion at 5 years? $150/3000=0.05$ What is the incidence rate after 5 years (rate)? $150/14625=0.01$ person per year			
	<b>Prevalence: Cross-sectional study (survey)</b> <ul style="list-style-type: none"> <li>One point in time; easy to measure</li> <li>Proportion or %</li> <li>Numerator: count of people with disease</li> <li>Denominator: count of total population</li> <li>No time component</li> </ul> Outcome has already developed and been ascertained	<b>Incidence: Cohort study &amp; RCT</b> <ul style="list-style-type: none"> <li>Involves time; difficult to measure.</li> <li>Measured as either rate or proportion</li> <li>Numerator: count of people who develop disease during follow-up</li> <li>Denominator:                         <ul style="list-style-type: none"> <li>(prop.) People at risk and</li> <li>(rate) Person-time at risk</li> </ul> </li> </ul> Newly developed during the course of study based on the time till outcome develops		

## Measures of Effect (Associations)

- Odds:** The ratio of the probability of occurrence of an event to that of non-occurrence.
  - Odds in Exposed =  $a/b$
  - Odds in Unexposed, "Baseline odds" =  $c/d$

		Outcome		
		Yes	No	Total
Exposure	Yes	a	b	a + b
	No	c	d	c + d
Total		a + c	b + d	N
- Odds ratio (OR):** Odds ratio =  $\frac{a/b}{c/d} = \frac{ad}{cb}$   
 important to know how to calculate odds ratio "see the practical lec" e.g. how we measure the strength of association between a rare hereditary disease and consanguinity? By odds ratio
- Risk:** Probability that an event will occur.
  - Risk in Exposed =  $a / (a+b)$
  - Risk in unexposed, "Baseline risk" =  $c / (c+d)$

		Outcome		
		Yes	No	Total
Exposure	Yes	a	b	a + b
	No	c	d	c + d
Total		a + c	b + d	N
- Relative Risk (RR):** Relative Risk =  $\frac{a/(a+b)}{c/(c+d)}$  important to know how to calculate RR "see the practical lec"  
 How many times more likely it is that someone who is exposed to something will develop a certain disease compared to someone who is not exposed.
  - 1 no difference between the groups.
  - <1 reduced the risk (protective).
  - >1 increase the risk

		Outcome		
		Yes	No	Total
Exposure	Yes	a	b	a + b
	No	c	d	c + d
Total		a + c	b + d	N

RR doesn't tell you the magnitude of benefit of treatment. It only tells there is increase or decrease risk in experiment group compared to control group.
- Absolute Risk Reduction (ARR):** (يهمني تعرفون الاحمر بس قالت بشكل عام مو مهم فاكيد قصدها حسابيا)
  - Risk Difference.
  - $ARR = RR (\text{exposed}) - RR (\text{Unexposed})$
  - It tells the magnitude of benefit and If ARR equals 0, then there is no difference between experiment and control.
  - Used in RCT.
  - Usually for protective effects while AR is for risk factors.

Example: if ARR = 15% in comparing ACEI vs placebo indecreasing IHD. This means if 100 patients were treated with ACEI, 15 cases of IHD can be prevented compared to placebo.
- Relative Risk Reduction (RRR):** (مو مطلوب منكم بس يهمني تعرفون انه) one of the measures of association of exposure and outcomes
  - $RRR = 1 - RR$
  - It tells how much the experiment treatment is reducing the chance of having outcome in single treated patient.

Example :if RRR = 70% in comparing ACEI vs placebo in decreasing IHD. This means treatment with ACEI will relatively reduce the risk of having IHD by 70% compared to placebo;
- Number Needed to Treat (NNT):** Number of persons who would have to receive an intervention (treatment) for 1 to benefit ( $NNT = 1/ARR$ )
- Number Needed to Harm (NNH)**

<b>Measures of Impact</b> Important to know that one of this measures AR and how to calculate AR	<ul style="list-style-type: none"> <li>Measures of association providing information about absolute effects of exposure.</li> <li>Reflect apparent contribution of an exposure to the frequency of disease.</li> <li><b>Attributable Risk (AR):</b> Quantifies disease burden in exposed group attributable to exposure</li> </ul> Provides answers to: 1) What is the risk attributed to the exposure? 2) What is the excess risk due to the exposure?
	<ul style="list-style-type: none"> <li>Calculated as risk difference (RD) = Risk (exposed) – risk (unexposed)</li> </ul>



# L4 Measures of Disease Frequency, Effect & Impact

## Measures for Disease Occurrence ( terms)

### **Proportions:**

Prevalence  
Incidence proportion

### **Rates:**

Incidence rates

### **Ratio:**

odds for a certain disease

### **Proportions :**

They are dimensionless (do not have a unit of measure, because the unit of measure in the denominator is the same as the numerator) - **Always lies between 0 and 1**

### **Rates :**

Denominator is measured in time units

Can exceed 1 if no. of new cases > person-time spent at risk

### **Ratio :**

Compares between two measures (two rates, odds or proportions)

What is counted in numerator isn't always in the denominator

# L5 Practical Session: Measuring Risk, Incidence & Prevalence

## Prevalence

<b>EXAMPLE 1</b>	in a survey of 1000 women who gave birth in a town X, at a given time, a total of 50 women had preterm labor.
<b>Answer 1 :</b>	<ul style="list-style-type: none"> <li>• Calculate the prevalence of preterm delivery in this group .</li> <li>- Numerator = 50 preterm deliveries.</li> <li>- Denominator = 1000 deliveries surveyed. <b>Prevalence = <math>50/1000 \times 100 = 5\%</math></b></li> </ul>
<b>Practical exercise 1</b>	Calculate the prevalence of cataract in a 15000 population aged between 60 to 70 years in the time period of summer months from June to August in city X, where 300 people were diagnosed to have cataract.
<b>Answer 1 :</b>	<b>Solution: <math>300 / 15000 \times 100 = 2\%</math></b>
<b>Practical exercise 2</b>	Calculate the point prevalence of 15 students suffering with influenza on a cold winter day on January 1st in a class of 100 students.
<b>Answer 2:</b>	<b>Solution: <math>15 / 100 \times 100 = 15\%</math></b>

## Calculating Incidence Rate

**Incidence** is the number of new cases of disease in a population.

<b>EXAMPLE 2 :</b>	In 2003, about 500 new cases of acquired immunodeficiency syndrome (AIDS) were reported in the country X. The estimated mid-year population of the country in 2003 was approximately 30,000.
<b>Answer 2:</b>	<b>Incidence rate = <math>(500/30000) \times 100 = 1.6 \%</math></b> <b>Alternatively can be expressed as 16 new cases of AIDS per 1000 population.</b>
<b>Practical exercise 3:</b>	The number of women having IGT was 2000 who were followed for a period of time. At the end of the follow up period -150 women were found to have been diagnosed as type 2 diabetes patients. Calculate the incidence rate.
<b>Answer 3:</b>	<b>Solution: <math>150 / 2000 \times 100 = 7.5\%</math></b>

## Calculating Attack Rate

<b>EXAMPLE 3</b>	In an outbreak of gastroenteritis among people who ate meals at a hotel, 99 persons ate raw salad, 30 of whom developed gastroenteritis.
<b>Answer 3:</b>	<ul style="list-style-type: none"> <li>• Calculate the <b>risk</b> of illness among persons who ate salad.</li> <li>- Numerator = Numerator = 30 persons who ate Salad and developed gastroenteritis.</li> <li>- Denominator = 99 persons who ate salad.</li> </ul> <b>Food-specific attack rate = <math>(30/99) \times 100 = 30.3\%</math></b>
<b>Practical exercise 4:</b> <b>+ Answer4</b>	The cholera investigation report found 22 persons to be positive for cholera among 200 persons who drank water from the same source . Calculate the attack rate. <b>Solution: <math>22 / 200 \times 100 = 11\%</math></b>

## Calculating Attributable risk

**Attributable Risk (AR)** is the difference in the disease rates in exposed and unexposed individuals.

<b>EXAMPLE 4 :</b>	<ul style="list-style-type: none"> <li>- Incidence of development of endometrial cancer in HRT group of women = 15%.</li> <li>- Incidence of development of endometrial cancer in non HRT group = 5%</li> </ul>
<b>Answer 4 :</b>	<b>Attributable risk = <math>15-5 = 10\%</math></b> <b>Therefore 10% of endometrial cancer is attributed to the HRT and can be prevented if the exposure factor is removed.</b>
<b>Practical exercise 5</b> <b>+ Answer 5 :</b>	Users of tobacco were surveyed for development of leukoplakia. Incidence of leukoplakia is given among the exposure group and the control group Calculate the attributable risk of the following: <ul style="list-style-type: none"> <li>- Incidence of leukoplakia among tobacco users = 19%.</li> <li>- Incidence of leukoplakia among non tobacco users = 5%. <b>Solution: <math>19-5 = 14\%</math></b></li> </ul>

# L5 Practical Session: Measuring Risk, Incidence & Prevalence

## Measures of association – relative risk - recommend you to study the lecture before the practical

### EXAMPLE 5

About 500 people complained of inflammation and fever, of which 400 reported wasp bites. Among the same number that served as controls, 200 still reported bites without symptoms and fever.

- Estimate the relative risk and determine the association between the exposure and the disease.

### Answer 5 :

Interpretation: the relative risk of 2.7 indicates that the risk of disease among the exposed group is 2.7 times that of the control group

**Relative Risk =  $(A / (A+B)) / (C / (C+D))$**

**$(A / (A+B)) = (400 / (400+200))$**

**$(C / (C+D)) (100 / (100+300))$**

**$(400 / 600) / (100 / 400) = (0.667/0.25) = 2.67$**

	Inflammation/ fever Yes	Inflammation/ fever No	Total
Wasp Bite( Yes)	400 (A)	200 (B)	600
Wasp Bite (No)	100 (C)	300 (D)	400
Total	500	500	1000

### Practical exercise 6 :

A total of 160 children underwent measles vaccination at a camp, of which 20 children from vaccinated group developed measles. While 5 from the control group developed the disease.

- Calculate the relative risk for the following and interpret what it means.

### Answer 6:

**Solution:  $20 / 160 \div 5 / 12 = 0.3 \times 100 = 30\%$  , protective effect due to vaccination.**

	Measles +	Measles -	Total
Vaccination	20	140	160
No vaccination	5	7	12
Total	25	147	172

# L6 Practical Session: Odds Ratio & Minimizing Bias

<b>Odds ratio AD/BC</b>	<p>measure of association between exposure and disease occurrence which shows the odds of developing disease risk in the exposed group when compared with unexposed group</p> <p>If the <b>OR is =1 ( no association)</b> ,If the <b>OR is &lt; 1 (negative association)</b> ,If the <b>OR is &gt;1( positive association )</b></p> <p>Case-control: we start with outcome, we can't calculate attack rate, use odds ratio instead of RR, and the population is unknown (differentiate between it and retrospective cohort)</p> <p>Formula of Odds ratio = AD/BC.</p>												
<b>Example</b>	<p>The number of fatal and survived cases of a standard and new treatment regimen is given below.</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td style="text-align: center;">Outcome Died</td> <td style="text-align: center;">Survived</td> <td style="text-align: center;">Total</td> </tr> <tr> <td style="text-align: center;">Exposure Standard treatment</td> <td style="text-align: center;">150 (A)</td> <td style="text-align: center;">250 (B)</td> </tr> <tr> <td style="text-align: center;">New treatment</td> <td style="text-align: center;">20 (C)</td> <td style="text-align: center;">100 (D)</td> </tr> <tr> <td style="text-align: center;">Total</td> <td style="text-align: center;">170 (A+C)</td> <td style="text-align: center;">350 (B+D)</td> </tr> </table>	Outcome Died	Survived	Total	Exposure Standard treatment	150 (A)	250 (B)	New treatment	20 (C)	100 (D)	Total	170 (A+C)	350 (B+D)
Outcome Died	Survived	Total											
Exposure Standard treatment	150 (A)	250 (B)											
New treatment	20 (C)	100 (D)											
Total	170 (A+C)	350 (B+D)											
<b>Odds ratio</b>	AD= (150 * 100) = 15000, BC = (250*20) = 5000 and OR= 15000/5000 = 3												
<b>Interpretation</b>	The odds of death is 3 times greater in the standard treatment compared to the new treatment regimen												
<b>Exercise 1</b>	<p>Data from a case-control study of 198 esophageal cancer cases and 754 community-based controls are shown below in the table. The exposure factor under study is smoking and details of smokers are as shown under. Calculate the odds of risk for the given scenario.</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td style="text-align: center;">Outcome Esophageal cancer +</td> <td style="text-align: center;">Esophageal cancer -</td> <td style="text-align: center;">Total</td> </tr> <tr> <td style="text-align: center;">Exposure Smokers</td> <td style="text-align: center;">96 (A)</td> <td style="text-align: center;">104 (B)</td> </tr> <tr> <td style="text-align: center;">Non-smokers</td> <td style="text-align: center;">102 (C)</td> <td style="text-align: center;">650 (D)</td> </tr> <tr> <td style="text-align: center;">Total</td> <td style="text-align: center;">198 (A+C)</td> <td style="text-align: center;">754 (B+D)</td> </tr> </table>	Outcome Esophageal cancer +	Esophageal cancer -	Total	Exposure Smokers	96 (A)	104 (B)	Non-smokers	102 (C)	650 (D)	Total	198 (A+C)	754 (B+D)
Outcome Esophageal cancer +	Esophageal cancer -	Total											
Exposure Smokers	96 (A)	104 (B)											
Non-smokers	102 (C)	650 (D)											
Total	198 (A+C)	754 (B+D)											
<b>Odds ratio</b>	= 5.88												
<b>Interpretation</b>	The odd of development of esophageal cancer is 5.9 times greater in smokers compared to non-smokers												
<b>Exercise 2</b>	<p>A case control study taking 200 subjects as cases and 400 controls was done to study the effect of tobacco smoke on coronary heart disease. About 112 developed CHD who also smoked and 88 who developed CHD had no exposure to smoking while 176 among the controls smoked but did not develop the disease. Draw a 2*2 table and calculate the odds of risk for the given data.</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td style="text-align: center;">Outcome CHD +</td> <td style="text-align: center;">CHD -</td> <td style="text-align: center;">Total</td> </tr> <tr> <td style="text-align: center;">Exposure smokers</td> <td style="text-align: center;">122</td> <td style="text-align: center;">176</td> </tr> <tr> <td style="text-align: center;">Non-smokers</td> <td style="text-align: center;">88</td> <td style="text-align: center;">224</td> </tr> <tr> <td style="text-align: center;">Total</td> <td style="text-align: center;">200</td> <td style="text-align: center;">400</td> </tr> </table>	Outcome CHD +	CHD -	Total	Exposure smokers	122	176	Non-smokers	88	224	Total	200	400
Outcome CHD +	CHD -	Total											
Exposure smokers	122	176											
Non-smokers	88	224											
Total	200	400											
<b>Odds ratio</b>	= 1.619												
<b>Interpretation</b>	The odd of development of CHD is 1.6 times greater in smokers compared to non- smokers												
<b>Exercise 3</b>	<p>Two classes consisting of 100 students in each were studied to determine the exposure of TV viewing and binge eating on obesity. A total of 75 obese cases were studied, among whom 50 had TV viewing with binge eating habit. Also 50 students from among the controls too had the habit. Draw the 2*2 table and determine the risk associated with the habit.</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td style="text-align: center;">Outcome Obese +</td> <td style="text-align: center;">Obese -</td> <td style="text-align: center;">Total</td> </tr> <tr> <td style="text-align: center;">Exposure TV viewing with binge eating habits +</td> <td style="text-align: center;">50</td> <td style="text-align: center;">50</td> </tr> <tr> <td style="text-align: center;">TV viewing with binge eating habits -</td> <td style="text-align: center;">25</td> <td style="text-align: center;">75</td> </tr> <tr> <td style="text-align: center;">Total</td> <td style="text-align: center;">75</td> <td style="text-align: center;">125</td> </tr> </table>	Outcome Obese +	Obese -	Total	Exposure TV viewing with binge eating habits +	50	50	TV viewing with binge eating habits -	25	75	Total	75	125
Outcome Obese +	Obese -	Total											
Exposure TV viewing with binge eating habits +	50	50											
TV viewing with binge eating habits -	25	75											
Total	75	125											
<b>Odds ratio</b>	= 3												
<b>Interpretation</b>	The odd of development of Obesity is 3 times greater in TV viewing with binge eating habits compared to No TV viewing with binge eating habits												

# L6 Practical Session: Odds Ratio & Minimizing Bias

## Bias in epidemiological studies - Minimizing Bias

Epidemiological studies are prone to bias; hence it is the duty of every epidemiologist to minimize bias in every step of design, planning and execution of studies.  
Types of bias: the three types of common bias : • Recall bias • Selection bias • Interviewer bias

## Recall bias

**Recall bias is a major problem in case control studies** as the subjects may face difficulties in recalling the vital information leading to serious distortion or errors in recording details.

Difficulty in recalling the information has led to **under estimation** of 'a' i.e., cases with exposure. Hence it leads to under estimation of OR.

	Leukemic children	Controls
Coffee consumption	A	B
Did not take	C	D

## Methods to reduce recall bias:

1-minimize the recall period. 2- Questionnaire Contain accurate questions to aid in quick recall. 3- Using information from records and other reliable sources of health department in order to reduce recall bias 4- Careful selection of controls with similar cultural and geographical features as that of cases, but different disease under study. 5- Confirming recorded information by verifying with close family members.

## Selection bias

Errors during recruiting study subjects may introduce selection bias. Selection of cases from a single hospital, or same economic strata or selection of complicated cases may distort results

## minimized by

1- The study population should be clearly defined. 2-Case definition and exposure definition must be clearly defined. 3-Selection of subjects must strictly adhere to selection criteria. 4-Selection of proper control or the unexposed group is of primary importance. 4- Controls (unexposed general population) 5- Controls (can be recruited from hospitals, neighborhood or relatives who do not have the disease under study. )

## Interviewer Bias

Bias can be introduced into the study by the interviewer at the time of recording information.

	Cancer	Controls
Exposure to pesticides	600	250
No Exposure to pesticides	400	750

Excessive probing has increased the exposed cases.



	Cancer	Controls
Exposure to pesticides	660	250
Mo exposure	340	750

$$OR = (600 \cdot 750) / (400 \cdot 250) = 4.5$$

$$OR = (660 \cdot 750) / (340 \cdot 250) = 5.8$$

## minimized by

1- Training interviewers . 2- small number of interviewers ( red. inter observer variation). 3- following a validated closed ended questionnaire. 4- Blinding the interviewers to exposure outcome of the study participant. 5- Blinding the subjects by not revealing the minute research details.

## Exercise 1

Consider the following scenario. A survey was done to probe the pesticide exposure to study the association with cancer. The interviewer excessively probed on the exposure to pesticide history and thereby increased the number of cancer cases with exposure history leading to overestimation of odds ratio. **Determine the type of bias introduced here and mention the methods to overcome it.**

outcome	Esophageal cancer +	Esophageal cancer -	Total
exposure			
Smokers	96	104	200
Non-smokers	102	650	752
Total	198	754	952



outcome	Esophageal cancer +	Esophageal cancer -	Total
exposure			
Smokers	126↑	104	239
Non-smokers	72	650	722
Total	198	754	952

## Solution

**OR has been overestimated from 5.8 to 10.9 . Type of bias: Interviewer bias**

## Interpretation

The odd of development of esophageal cancer is 5.9 times greater in smokers compared to non-smokers

## Exercise 1

Mothers of children with congenital defects fail to recollect the dietary or drug history during pregnancy leading to underestimation of OR. **What is type of bias that is related to this scenario and provide its solution.**

outcome	Congenital defect babies +	Congenital defect babies -	Total
exposure			
drug history +	60	50	
drug history -	30	65	
Total			



outcome	Congenital defect babies +	Congenital defect babies -	Total
exposure			
drug history +	40 ↓	50	
drug history -	50	65	
Total			

## Solution

**OR has been underestimated from 2.5 to 1.04 . Type of bias: Recall bias**

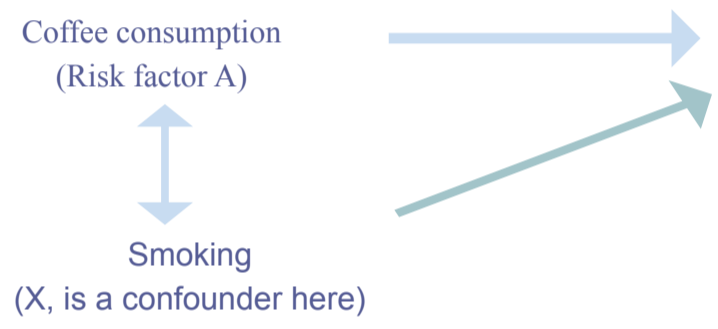
# L7 Practical Session: Relative Risk, Confounding

## Relative Risk

Relative risk helps in identifying the risk of developing a disease in an exposed group versus risk of developing a disease in the non exposed group. **AKA incidence, and it's only measured for cohort studies.**  
**Relative risk =  $A/(A+B)/C/(C+D)$ .**

## Confounding

- It is a situation in which a measure of the effect of an exposure is **distorted** because of the association of exposure with other factor or factors that influence the outcome of interest. **Common errors decrease when the sample size increase, on the other hand confounders doesn't decrease.**
- It can be described as:**
  - Factor A is a risk factor for Disease B.
  - X is a confounder if it is a risk factor for Disease B and is also associated with Factor A.
  - Ask yourself 3 questions:**
    - Is it a known risk factor for the outcome?
    - Is it associated with the exposure?
    - Is it NOT a result of the exposure?
- Example:**
  - In the study of whether coffee consumption is a risk factor for pancreatic cancer, smoking is a confounder if:
    - It is a known risk factor for pancreatic cancer
    - It is associated with coffee drinking but is not a result of coffee drinking.



**Extra Explanation:**

- Confounding bias is **unmeasured factor** that confound study result.
- Suppose we take the previous example where coffee consumption appears to be a risk factor for pancreatic cancer → however, smoking is more prevalent among coffee consumers → smoking is the true cause of pancreatic cancer, therefore it's a confounder of results.

## Example

- To study if baldness causes CHD in men, an epidemiological study recruited 10000 bald and 10000 hairy men and followed for 10 years to see for CHD.

	CHD	No CHD	Total
Bald	775	9225	10000
Hairy	190	9810	10000
Total	965	19035	20000

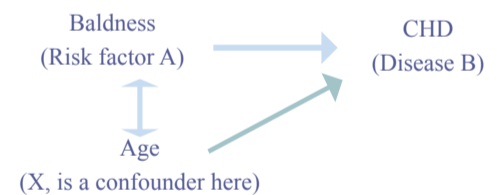
**Older subjects (>65 years)**

	CHD	No CHD	Total
Bald	750	6750	7500
Hairy	100	900	1000
Total	850	7650	8500

RR in the older men:  $(750/7,500)/(100/1,000) = 1$

**Extra Explanation:**

- To understand how to discover confounders, we need to understand first the concept of stratified analysis which eliminate confounding bias:
  - In the previous study we were looking whether baldness causes CHD in men and the RR= 4.08, however when we stratified the result by age we got RR= 1 in both groups, which means that age has eliminated the effect of baldness on CHD, therefore it's a confounder.
  - Simply, if the RR goes away ones you split up the results into subgroups, that means there was a confounder affecting the initial results.



- RR associated with baldness =  $(775/10,000)/(190/10,000) = 4.08$
- So the risk of CHD in bald men is 4.08 times more than in hairy men. This is a strong association but can we say if this is due to causal relationship or due to confounding effect.

**Younger subjects (40-64 years)**

	CHD	No CHD	Total
Bald	25	2475	2500
Hairy	90	8910	9000
Total	115	11385	11500

RR in the younger men:  $(25/2,500)/(90/9,000) = 1$

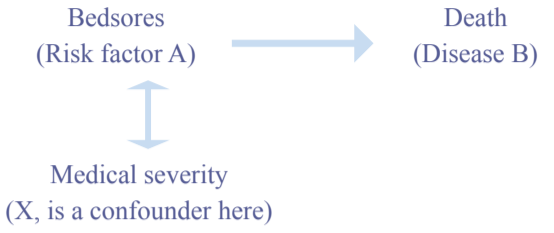
- These results suggest that there is confounding by age since because when stratifying and adjusting for age the risk is changed. Had there been no effect from confounding then the risk would have been 4 even after stratifying.**
- Thus age is a confounder in this study.**

# L7 Practical Session: Relative Risk, Confounding, Contd..

## Scenario 1

- Patients with bedsores and death. This study was carried out in 9400 patients among people aged 60 and above. Records of patients with and without bed sores were examined for outcome.
- Calculate the risk and determine whether medical severity( high & low) is a confounder ?
  - The RR= 1, thus medical severity is a confounder

	Died	Didn't die <sup>1</sup>	Total
Bedsore	79	745	824
No bedsore	286	8290	8576
Total	365	9035	9400



- Tip: Whenever you calculate RR, strike the second column (which is not used) to avoid confusion.
- An easy template to interpret your RR result:
  - The risk of (disease) among (exposed) is (RR) times among (non exposed)

- RR= (79/824)/(286/8576) = 2.87
  - The risk of death in bed sore is 2.87 times compared to non bed sores.

**Risk of bed sores and death in high medical severity group**

	Died	Didn't die	Total
Bedsore	55	51	106
No bedsore	5	5	10
Total	60	56	116

**Bedsore and death in low medical severity group**

	Died	Didn't die	Total
Bedsore	24	694	718
No bedsore	281	8285	8566
Total	305	8979	9284

- RR= (55/106)/(5/10) = 1.037
  - No Relationship

- RR= (24/718)/(281/8566) = 1.018
  - No Relationship

## Scenario 2

- Case control study<sup>1</sup>** discussing diabetes, CHD and age. The variable: age is a universal confounder and its effect shall be discussed subsequently.

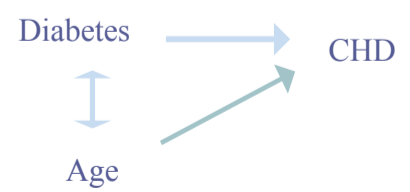
- Case control study measures Odds Ratio NOT Relative Risk.
- An easy template to interpret your OR result:
  - The odds of (exposure) among (disease) is (OR) times than (non disease)

	CHD	No CHD
Diabetes	30	18
No diabetes	70	82
Total	100	100

- OR= (30\*82)/(18\*70) = 1.95
  - The odds of diabetes among CHD is 1.95 times than non CDH.

- Question:** Draw the diagram showing causal association between the variables. With the given data, determine, whether age(<40 & ≥ 40 is a confounder).

	Exposed	Cases YES	Cases NO	Odds ratio
Age <40	Yes	5	8	RR= 1
	No	45	72	
Age ≥ 40	Yes	25	10	RR= 1
	No	25	10	



- RR of Age<40= (5/(5+8))/(45/(45+7)) = 1

- RR of Age ≥40= (25/(25+10))/(25/(25+10)) = 1

→ The effect of the overall relationship was nullified on stratification, which means that the effect was due to confounding.

# L8 Introduction to Study Designs

<b>Definition</b>	A study design is a detailed plan or approach for systematically collecting, analyzing, and interpreting data; it is a formal approach of scientific investigation.
categories of or ways of epidemiological study designs:	Descriptive studies: 1- <b>What= Outcome</b> of interest (Diagnosis), 2- <b>Who= Population</b> of interest, 3- <b>Where= Place</b> , 4- <b>When= Time</b>
	<b>Analytical studies: Why / How(Q)=</b> Exposures / Risk Factors / Mode of Transmission

Remember **PICOT**

**ALL** research questions (**Descriptive AND Analytical**) have the below similar components:

- **defined population (P)** from which groups of subjects are studied
- **Outcomes (O)** that are measured
- **Time (T)** frame

**ANALYTICAL** research questions have the additional two components:

- **Intervention (I)** that is applied to a groups of subjects
- **Comparison (C)** group without the intervention

**Generates Hypotheses**

- Descriptive (PO)
  - Case report
  - Case series
  - Cross-sectional (survey)
  - Qualitative
- Experimental
  - Randomized Clinical Trials (RCTs)

**Tests Hypotheses**

- Analytical (PICO)
  - Observational
    - Group data
      - Ecological study
    - Individual
      - Cross-sectional (analytical)
      - Cohort
      - Case-Control

Whether a topic requires a hypothesis-testing or hypothesis-generating study depends on:	1. What types of studies have already been conducted
	2. The present state of knowledge <ul style="list-style-type: none"> <li>• What do we know about the outcome of interest?</li> <li>• What if any risk factors have been investigated?</li> </ul>

**Two important distinctive Factors in Study Designs:**

- 1- **Quantification of Relationship** between Exposure and Outcome
- 2- **Researcher Assignment (Manipulation) of Exposure**

Quantification of the relationship

No ——— Descriptive

Yes ——— Analytical

Assignment of the Exposure by Researcher

Yes ——— Experimental (RCT)

No ——— Observational

الفكرة بسيطة اسئل نفسك هل في علاقه مقارنه او فيه تدخل منك؟ لا بتكون ديسكربتيف ايه فيتكون انلايتك هل راح تعطلي دواء بنفسك او اللقاح تبع البحث؟ اي بيكون تجريبي So

<b>Sequence of study design:</b>	<b>Descriptive:</b> Identifying hypotheses to test in analytic Studies	<b>Analytical – Observational CASE-Control :</b> Evaluate if the hypothesized exposure is <u>related</u> to the outcome of Interest	<b>Analytical – Observational Cohort:</b> Further define the importance of exposure for the development of Outcomes	<b>Analytical – Experimental RCT :</b> Test the <u>actual link</u> between exposure and outcome. i.e.causality
	From observational studies we can infer causal relationships, from experimental studies we can confirm causal relationships.			

**Descriptive Studies**(focus on the first 2 the others will be explained in single lecture and after you study their lectures come and read this table)

Study Design	Case Report	Case Series	Cross-Sectional (Survey)	Qualitative
Study Population	Single case	Collection of similar cases( <b>more than 1 less than 60</b> )	Single sample from larger population – No comparison	Process of naturalistic inquiry that seeks in-depth understanding of phenomena within their natural setting (Individual, societies, languages)
Primary use	<ul style="list-style-type: none"> <li>Detailed report of the symptoms, signs, diagnosis, treatment, and <b>follow-up of an individual patient.</b></li> <li>Typically an <b>unusual/novel occurrence</b></li> </ul>	Detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of a <b>group of patients or cases with similar issue.</b>	<ul style="list-style-type: none"> <li>Study <b>prevalence</b> of health related events at a <b>point in time/snapshot</b></li> <li>Often used to study conditions that are relatively frequent with long duration of expression (nonfatal, chronic conditions)</li> </ul>	Answers the 'why?' questions
Advantages	<ul style="list-style-type: none"> <li>Detecting novelties</li> <li>Generating hypotheses</li> <li>Allowing in-depth understanding</li> <li>Educational value</li> </ul>	<ul style="list-style-type: none"> <li>Useful for hypothesis generation</li> <li>Informative for very rare disease with few established risk factors</li> </ul>	<ul style="list-style-type: none"> <li>Cheap and simple.</li> <li>Ethically safe.</li> </ul>	<ul style="list-style-type: none"> <li>Provides depth and detail</li> <li>Creates openness</li> <li>Simulates people's individual experiences</li> </ul>
Dis-advantages	<ul style="list-style-type: none"> <li>Lack of ability to generalize</li> <li>No possibility to establish cause-effect relationship</li> <li>Publication bias</li> </ul>	<ul style="list-style-type: none"> <li>Cannot study cause and effect relationships</li> <li>Cannot assess disease frequency</li> </ul>	Not suitable for studying <b>rare</b> or highly fatal diseases or a <b>disease with short duration</b>	<ul style="list-style-type: none"> <li>Usually fewer people studied</li> <li>Less easy to generalize</li> <li>Dependent on skills of the researcher</li> </ul>



# L8 Introduction to Study Designs

## Analytical Studies

	Experimental	Observational			
Data Level	Individual Data	Group Data	Individual Data		
Study Design	RCT	Ecological	Cross-Sectional	Cohort	Case-Control
Study Population	Highly selected population, Highly controlled environment. Allocation of exposure is made by the researcher.	Population based study (city, country, geographic area). Usually <b>using secondary data</b> .	Single sample from larger population – compares two groups in the sample	Two samples – <u>Exposed</u> group and <u>Not Exposed</u> . <b>NO</b> allocation of exposure is made by the researcher	Two samples – group <u>With Outcome</u> (DISEASE) and group <u>Without Outcome</u> (NO DISEASE)
Directionality <small>when exposure and outcome assigned or measured</small>	Exposure is <b>assigned BEFORE</b> Outcome is <u>measured</u>	Exposure and Outcome <b>BOTH measured at the SAME TIME</b> at POPULATION level	Exposure and Outcome <b>BOTH measured at the SAME TIME</b> at INDIVIDUAL level	Exposure is <u>measured</u> BEFORE Outcome is <u>measured (prospectively)</u>	Outcome is <u>measured</u> BEFORE Exposure is <u>measured</u>
Primary Use	Efficacy of an intervention / <u>Causality</u>	Screening hypotheses at population level (BE AWARE of Ecological Fallacy)	Screening hypotheses at individual level, <u>Prevalence studies</u>	Assessing associations between exposures and outcomes <u>over time</u>	Assessing associations between exposures and <u>rare outcomes (rare diseases)</u>

Examples of Analytical Studies	<p>1-<b>Ecological</b>: Compares cases of flu and flu vaccine in two countries</p> <p>2-<b>Cross-Sectional</b>: KKUH hospital flu cases and vaccination status in females vs males</p> <p>3-<b>Case-Control</b>: Comparing a group of flu cases to non-cases based on vaccination status</p> <p>4-<b>Cohort</b>: Following vaccinated and non-vaccinated groups over time to see if they get the flu</p> <p>5-<b>Experimental – RCT</b>: Same as cohort but researcher randomly allocates the flu vaccine</p>
--------------------------------	---

The type of study can be determined by looking at **three factors** (as per the “Design Tree”):

Q1. **What was the aim of the study?**

- To simply describe a population (PO questions) —>**Descriptive**
- To quantify the relationship between exposure & outcome (PICO questions) —>**Analytic**

Q2. **If analytic, was the intervention randomly allocated (assigned by the researcher)?**

- Yes —>**Experimental**
- No —> **Observational**

Q3. **If Observational, When were the outcomes determined (measured)?**

- At the **same time** as the exposure (intervention) —>**Cross-sectional**
- Before** the exposure was measured —>**Case-Control**
- Some time **after** the exposure (intervention) —>**Cohort study**

# L9 Cross sectional study design

<b>Definition</b>	A cross-sectional study is a study that quantifies an outcome of interest <b>AND/OR</b> examines the relationship between disease (or other health related state) and other variables of interest as they exist <b>in a defined population at a single point in time.</b>																																
<b>Uses</b> (when to conduct)	<ul style="list-style-type: none"> <li>- <b>To estimate prevalence (burden) of a health condition (disease)</b> or prevalence of a behavior or risk factor</li> <li>- <b>To learn about characteristics such as knowledge, attitude and practices of individuals in a population</b></li> <li>- To monitor trends over time with serial cross-sectional studies (e.g. in the US the National Health and Nutrition Surveys (NHANES)).</li> <li>- Hypothesis generation about cause of disease</li> </ul>																																
<b>Types</b>	<b>Descriptive</b>	<b>Analytical (there is a comparison)</b>																															
	<ul style="list-style-type: none"> <li>- Study prevalence of health related events at a point in time/snapshot (e.g. diseases, risk factors, interventions, health service utilization, knowledge, attitudes and practice)</li> <li>- Prevalence on an outcome</li> <li>- <b>Simply characterize the prevalence of a health outcome in a specified population.</b></li> </ul>	<ul style="list-style-type: none"> <li>- <b>Assess association between exposure and outcome.</b></li> <li>- Exposure and disease status are assessed <b>simultaneously</b> among individuals at the same point in time</li> <li>- <b>Compare prevalence</b> of an outcome (disease) between exposed and unexposed</li> <li>- They <b>compare the proportion</b> of exposed persons who are diseased with the proportion of non-exposed persons who are diseased</li> </ul>																															
<b>Formulas</b> Measurement & Analysis in Cross-Sectional studies	<b>Prevalence = Cases / Total Population X 100</b>	<b>Prevalence Odds Ratio (POR)</b>																															
	<p>You identify a random sample of young adults aged 18 – 25 in city of Riyadh.</p> <table border="1"> <thead> <tr> <th></th> <th>Vaping (Outcome)</th> <th>Not Vaping (Outcome)</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>Ads (Exposure)</td> <td>50</td> <td>200</td> <td>250</td> </tr> <tr> <td>No Ads (Exposure)</td> <td>50</td> <td>700</td> <td>750</td> </tr> <tr> <td><b>Total</b></td> <td><b>100</b></td> <td><b>900</b></td> <td><b>1000</b></td> </tr> </tbody> </table> <p><b>Descriptive Cross-Sectional:</b> What is the prevalence of vaping? Number of people who vape/ Total population X 100 = 100 /1000 X 100 = 10%</p>		Vaping (Outcome)	Not Vaping (Outcome)	Total	Ads (Exposure)	50	200	250	No Ads (Exposure)	50	700	750	<b>Total</b>	<b>100</b>	<b>900</b>	<b>1000</b>	<p>Does the prevalence of vaping vary by the status of exposure to advertisement? <b>Analytical Cross-Sectional:</b> i.e. What are the <b>odds</b> of vaping given exposure to advertisement?</p> <table border="1"> <thead> <tr> <th></th> <th>Vaping (Outcome)</th> <th>Not Vaping (Outcome)</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>Ads (Exposure)</td> <td>50 (A)</td> <td>200 (B)</td> <td>250</td> </tr> <tr> <td>No Ads (Exposure)</td> <td>50 (C)</td> <td>700 (D)</td> <td>750</td> </tr> <tr> <td><b>Total</b></td> <td><b>100</b></td> <td><b>900</b></td> <td><b>1000</b></td> </tr> </tbody> </table> <p><b>POR</b> = odds an exposed person develop the outcome (a/b) odds an unexposed person develop the outcome (c/d) <b>= ad / bc</b> = (50X700) / (200X50) = 3.5</p> <p><b>What does a POR of 3.5 mean?</b> The odds of vaping is 3.5 times higher among those who have seen a vaping advertisement compared to those who haven't.</p>		Vaping (Outcome)	Not Vaping (Outcome)	Total	Ads (Exposure)	50 (A)	200 (B)	250	No Ads (Exposure)	50 (C)	700 (D)	750	<b>Total</b>	<b>100</b>	<b>900</b>
	Vaping (Outcome)	Not Vaping (Outcome)	Total																														
Ads (Exposure)	50	200	250																														
No Ads (Exposure)	50	700	750																														
<b>Total</b>	<b>100</b>	<b>900</b>	<b>1000</b>																														
	Vaping (Outcome)	Not Vaping (Outcome)	Total																														
Ads (Exposure)	50 (A)	200 (B)	250																														
No Ads (Exposure)	50 (C)	700 (D)	750																														
<b>Total</b>	<b>100</b>	<b>900</b>	<b>1000</b>																														
<b>How to conduct?</b> (steps)	<ul style="list-style-type: none"> <li>- Define a <b>population</b> of interest (reference or source population)</li> <li>- Recruit a representative <b>sample</b> ((adequate size, random selection)</li> </ul>	<ul style="list-style-type: none"> <li>- Measure the <b>variables</b> of interest (exposure/outcome) at the same point in time</li> <li>- Analyze the <b>data</b></li> </ul>																															

## Identify Subjects from population

(The participants in a cross-sectional study are selected based on the **inclusion and exclusion criteria** set for the study)

## Collect data on exposure and outcome (e.g. disease)

Exposed and have a disease	Not exposed and have a disease	Exposed and do not have a disease	Not exposed and do not have a disease
----------------------------	--------------------------------	-----------------------------------	---------------------------------------

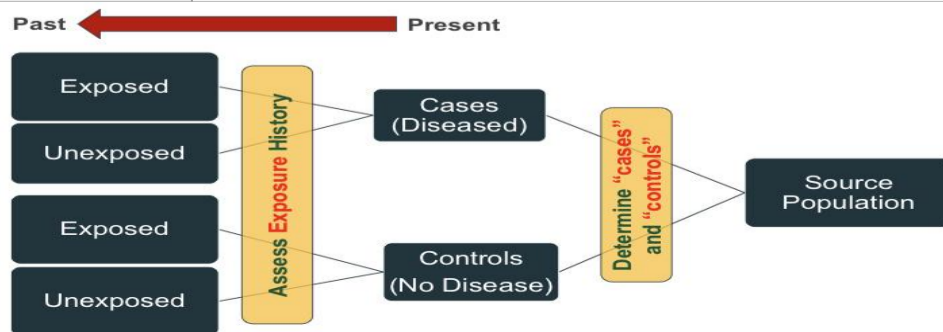
<b>Strengths</b>	<ul style="list-style-type: none"> <li>- Relatively quick and easy to conduct</li> <li>- Multiple outcomes and exposures can be studied.</li> <li>- Data on all variables is only collected once</li> </ul>	<ul style="list-style-type: none"> <li>- Able to measure prevalence for all factors under investigation</li> <li>- Good for describing and for generating hypotheses.</li> </ul>
<b>Weakness</b>	<ul style="list-style-type: none"> <li>- <b>Difficult to determine temporality</b> between exposure and outcome.</li> <li>- Associations identified may be difficult to interpret.</li> </ul>	<ul style="list-style-type: none"> <li>- <b>Susceptible to bias</b> due to low response and misclassification due to recall bias.</li> </ul>
<b>Study Sample</b>	<ul style="list-style-type: none"> <li>- Should be large enough to estimate prevalence of the conditions of interest with adequate precision and representative of the population.</li> </ul>	

<b>Biases in Cross-Sectional Studies</b>	<p>Bias may be defined as any <b>systematic difference</b> between groups in an epidemiological study that results in an incorrect estimate of the true effect of an exposure on the outcome of interest.</p> <ol style="list-style-type: none"> <li>1. Selection Bias (sampling bias)</li> <li><b>2. Recall bias</b></li> </ol>
--	--

<b>Confounding</b>	<p>Occurs when an observed association is in fact distorted because the exposure (x) is correlated with another risk factor(y) which is also associated with the outcome (o).</p> <ol style="list-style-type: none"> <li>1. Associated with exposure</li> <li>2. Causing the outcome</li> <li>3. Does not lie in the causal pathway</li> </ol>	
--------------------	--	--

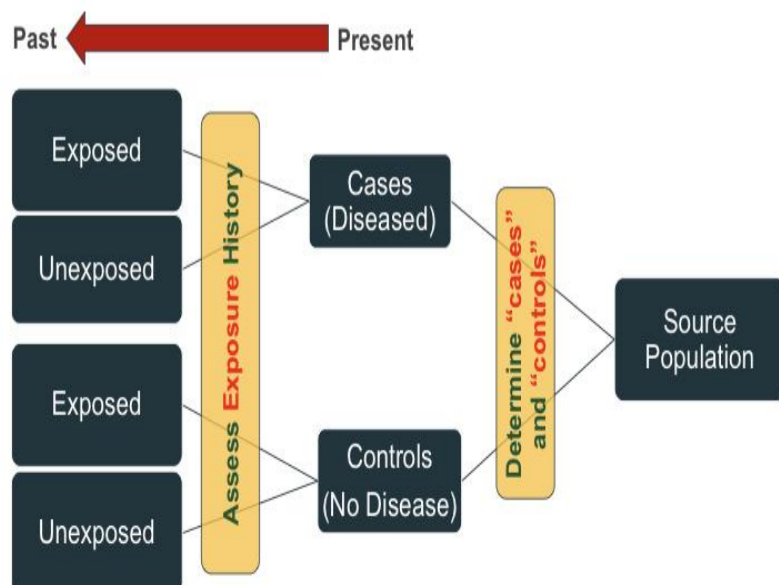
# L10:case-control studies

<p><b>Def</b></p> <p><b>When?</b></p> <p><b>Steps:</b> Design:</p>	<p>study that compares subjects who have a disease or outcome of interest (cases) with subjects who do not have the disease or outcome (controls) by looking back <b>retrospectively</b> at the frequency of <b>exposure to a risk factor in each group</b>.</p> <p>-The <b>outcome</b> of interest is <b>rare</b>/-<b>Multiple exposures</b> may be associated with a <b>single outcome</b>. -Funding or time is limited: 1) To investigate cause-effect when experimental trials are not ethical or feasible (lung cancer and smoking), 2) To investigate cause-effect when cohort studies are expensive or non-feasible</p> <p><b>1- Define a source population</b> <b>5 - Decide on Matching Cases and Controls</b> <b>6- Estimate sample size</b> <b>7- Select Cases and Controls</b> <b>8- Measure Exposure (Risk Factor(s))</b></p> <table border="1" data-bbox="220 680 2039 1056"> <thead> <tr> <th colspan="2">Sources for Cases</th> <th>Selection of Cases</th> </tr> </thead> <tbody> <tr> <td>Hospital-Based</td> <td>Cases admitted to or discharged from a hospital, clinic or any health care facility.</td> <td rowspan="5">                     1) Establish a “standard case definition”: adopt a “standard diagnostic criteria”                      2) Set inclusion and exclusion criteria: Area of residence, age, gender, etc                      3) Decide on the <u>type of cases</u>:                     <ul style="list-style-type: none"> <li>• <b>incident</b> cases (newly diagnosed cases)</li> <li>• <b>prevalent</b> cases ((people who may have had the disease for some time)</li> </ul> </td> </tr> <tr> <td rowspan="4">Population-based</td> <td>Death certificates with recorded cause of death.</td> </tr> <tr> <td>Disease registries (e.g. Cancer registry)</td> </tr> <tr> <td>Incident cases in ongoing cohort study</td> </tr> <tr> <td>Cases reported or diagnosed during a survey or surveillance system</td> </tr> <tr> <td>Employment records</td> </tr> </tbody> </table> <p><b>2- Determine Study</b> <b>Subjects: “Cases”</b> (Case-subjects: They have the disease or outcome of interest)</p> <p><b>3-Determine Study</b> <b>Subjects: “Controls”</b> 1-Free from the outcome under investigation 2-Free from health problems associated with the exposure under investigation 3-Comparable to cases in terms of susceptibility</p> <p><b>Aim:</b> compare the exposure rate among those with outcome and those without ,<b>confirm/refute</b> if that the risk factor has occurred more frequently among the cases vs the controls using a measurement of association. <b>Selection of Controls:</b>Ideal controls are healthy ones/ It is crucial to select control group from population we are certain <b>do not</b> have the specified disease / condition.</p> <table border="1" data-bbox="895 1284 1768 1558"> <thead> <tr> <th colspan="2">Hospital-Based Controls</th> <th colspan="2">Community-Based Controls</th> </tr> <tr> <th>Advantages</th> <th>Disadvantages</th> <th>Advantages</th> <th>Disadvantages</th> </tr> </thead> <tbody> <tr> <td>                     1. Subjects are easily accessible.                      2. Patients usually have time to participate.                      3. Patients are often motivated to cooperate with investigators.                      4. Controls and cases may be drawn from similar social and geographical environment.                      5. Minimize recall bias because they are sick, but with a different diagnosis.                 </td> <td>                     1. Differing hospitalization patterns may introduce selection bias.                      2. Difficult to blind disease status from cases and controls.                      3. May have disease that share risk factors with outcome of interest (Berkson's bias).                 </td> <td>                     1. Reduction of selection bias.                      2. Generalization of study results is more valid.                      3. More likely to be healthy.                 </td> <td>                     1. Time and money consuming.                      2. May suffer low participation rate.                      3. Cases and control may exhibit differential recall of prior exposures.                 </td> </tr> </tbody> </table> <p><b>4-Decide on the Ratio of Cases to Controls</b></p> <p>The ratio of cases to control should be <b>at least and ideally 1:1</b>,However, in many situations we may not be able recruit a large number of cases and it may be easier to recruit more controls for the study. we can increase the number of controls to increase statistical power (if we have limited number of cases) of the study. <b>Increase in the ratio lead to increase in “study precision”</b>: 1:2, 1:3, 1:4 ,Further increase in the ratio is associated with little increase in study precision relative to the cost involved</p> <p><b>5-Decide on Matching Cases and Controls</b></p> <p>major concern in conducting a case-control study is that cases and controls may differ in characteristics or exposures other than the one that has been targeted for study. <b>Matching</b> is the <b>process of selecting the controls so that they are similar to the cases in certain characteristics</b> (confounders), such as age, race, gender, socioeconomic status,and occupation). <b>it reduces the possible confounding effect.</b> -Matching on several characteristics is not advisable as it: Creates difficulties in finding controls /Requires more complex statistical analysis/result in overmatching</p> <p><b>9-Analysis in Case-Control Studies</b></p> <p>The <b>odds ratio</b> (OR) is used in case-control studies to estimate the strength of the association between exposure and outcome. The odds ratio is a measure of the odds of disease in the exposed compared to the odds of disease in the unexposed and is calculated as: <math>OR = ad/bc</math> -<b>OR</b> interpretations: <math>OR &gt; 1</math>, <math>OR = 1</math>, <math>OR &lt; 1</math></p>	Sources for Cases		Selection of Cases	Hospital-Based	Cases admitted to or discharged from a hospital, clinic or any health care facility.	1) Establish a “standard case definition”: adopt a “standard diagnostic criteria” 2) Set inclusion and exclusion criteria: Area of residence, age, gender, etc 3) Decide on the <u>type of cases</u> : <ul style="list-style-type: none"> <li>• <b>incident</b> cases (newly diagnosed cases)</li> <li>• <b>prevalent</b> cases ((people who may have had the disease for some time)</li> </ul>	Population-based	Death certificates with recorded cause of death.	Disease registries (e.g. Cancer registry)	Incident cases in ongoing cohort study	Cases reported or diagnosed during a survey or surveillance system	Employment records	Hospital-Based Controls		Community-Based Controls		Advantages	Disadvantages	Advantages	Disadvantages	1. Subjects are easily accessible. 2. Patients usually have time to participate. 3. Patients are often motivated to cooperate with investigators. 4. Controls and cases may be drawn from similar social and geographical environment. 5. Minimize recall bias because they are sick, but with a different diagnosis.	1. Differing hospitalization patterns may introduce selection bias. 2. Difficult to blind disease status from cases and controls. 3. May have disease that share risk factors with outcome of interest (Berkson's bias).	1. Reduction of selection bias. 2. Generalization of study results is more valid. 3. More likely to be healthy.	1. Time and money consuming. 2. May suffer low participation rate. 3. Cases and control may exhibit differential recall of prior exposures.
Sources for Cases		Selection of Cases																							
Hospital-Based	Cases admitted to or discharged from a hospital, clinic or any health care facility.	1) Establish a “standard case definition”: adopt a “standard diagnostic criteria” 2) Set inclusion and exclusion criteria: Area of residence, age, gender, etc 3) Decide on the <u>type of cases</u> : <ul style="list-style-type: none"> <li>• <b>incident</b> cases (newly diagnosed cases)</li> <li>• <b>prevalent</b> cases ((people who may have had the disease for some time)</li> </ul>																							
Population-based	Death certificates with recorded cause of death.																								
	Disease registries (e.g. Cancer registry)																								
	Incident cases in ongoing cohort study																								
	Cases reported or diagnosed during a survey or surveillance system																								
Employment records																									
Hospital-Based Controls		Community-Based Controls																							
Advantages	Disadvantages	Advantages	Disadvantages																						
1. Subjects are easily accessible. 2. Patients usually have time to participate. 3. Patients are often motivated to cooperate with investigators. 4. Controls and cases may be drawn from similar social and geographical environment. 5. Minimize recall bias because they are sick, but with a different diagnosis.	1. Differing hospitalization patterns may introduce selection bias. 2. Difficult to blind disease status from cases and controls. 3. May have disease that share risk factors with outcome of interest (Berkson's bias).	1. Reduction of selection bias. 2. Generalization of study results is more valid. 3. More likely to be healthy.	1. Time and money consuming. 2. May suffer low participation rate. 3. Cases and control may exhibit differential recall of prior exposures.																						



# L10:case-control studies

<p><b>Issues</b></p>	<ul style="list-style-type: none"> <li>• <b>Formulation of a clearly defined hypothesis, case, and sources</b></li> <li>• Bias:             <ol style="list-style-type: none"> <li>1- selection Bias</li> <li>2-Ascertainment Bias                 <ul style="list-style-type: none"> <li>- Cases may recall exposure better (recall bias)</li> <li>- Investigators may search for exposure more thoroughly in cases (observer bias)</li> <li>- Different data collection instrument may be used for the controls</li> </ul> </li> <li>3- <b>Confounding</b>: A confounding variable is one that is associated with both the exposure and the outcome.                 <ul style="list-style-type: none"> <li>• <u>Measuring exposure status</u>:established after the development of disease “retrospectively”/ As a result is prone to both recall and observer bias.</li> </ul> </li> </ol> </li> </ul> <p><b>Various methods can be used to ascertain exposure status, including:</b></p> <ul style="list-style-type: none"> <li>• Standardized questionnaires • Biological samples • Interviews with the subject • Interviews with spouse or other family members • Medical records • Employment records • Pharmacy records</li> <li>- The procedures used for the collection of exposure data should be <b>the same</b> for <i>cases</i> and <i>controls</i>.</li> </ul>
<p><b>Strengths</b></p>	<p>Cost effective /no long follow up period /Efficient for the study of diseases with long latency periods/Efficient for the study of rare diseases/ Good for <b>examining multiple exposures</b>.</p>
<p><b>Weakness</b></p>	<p>Particularly prone to bias; <b>especially selection, recall and observer bias</b>. /limited to examining one outcome/Unable to estimate incidence rates of disease (unless study is population based)/<b>Poor choice for the study of rare exposures</b>.</p>



# L11 Cohort Study Design

- A cohort study is an **analytical observational study** in which a **group of people** with a common characteristic is **followed over time** to find how many reach a certain health outcome of interest (disease, condition, event, death, or a change in health status or behavior).
- Term "cohort" is defined as a group of people, **usually 100 or more in size**, who share a common characteristic or experience within a defined time period (e.g., age, occupation, exposure to a drug or vaccine, pregnancy, and insured persons).
- **The comparison group** may be the general population from which the cohort is drawn, or it may be another cohort of persons thought to have had little or no exposure to the substance in question, but otherwise similar.

2 types ( [For more understanding click here](#) )

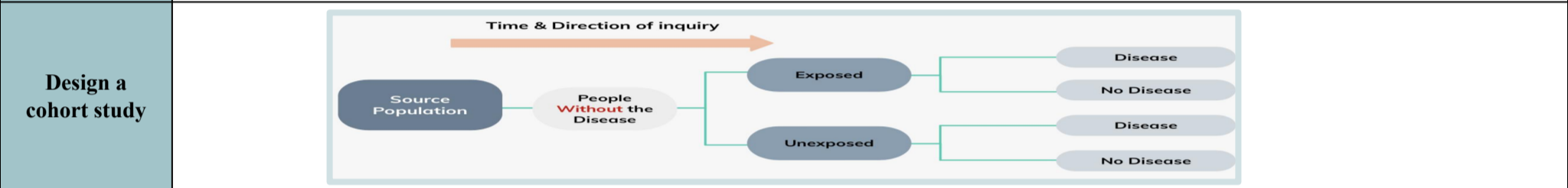
cohort studies have been distinguished on the **basis of the time of occurrence of disease** in relation to the time at which the **investigation is initiated**

<b>Prospective</b>		<b>Retrospective</b>	
--------------------	--	----------------------	--

في نفس الزمن تختار قروب وتبدأ تراقبهم كل سنة او 5 او..وصعب لانه يمكن تخسر بعضهم

ترجع بالزمن للوراء وتكمل دراسة قدام كانك كنت بعصرهم وبديت وقتها تدرسهم

<b>When to conduct a cohort study</b>	<ul style="list-style-type: none"> <li>◦ When there is <b>good evidence of an association</b> (we benefit from more than cross sectional and case control studies) between <b>exposure and disease</b> (If we observe an association between an exposure and a disease or another outcome, the question is: Is the association causal?).</li> <li>◦ <b>When exposure is rare</b>, but the incidence of disease high among exposed, e.g. special exposure groups like those in industries, or exposure to X-rays. however, <b>when the outcome is rare --&gt; case control</b></li> <li>◦ When attrition (loss during follow up) of study population can be minimized, e.g. follow-up is easy, cohort is stable, cooperative and easily accessible</li> <li>◦ When funds &amp; time are available (feasible)</li> </ul>
---------------------------------------	--



<b>Steps in conducting:</b>	<ol style="list-style-type: none"> <li>01. Define a source population.</li> <li>02. Select study populations: "Subjects and controls" : <ul style="list-style-type: none"> <li>◦ Two methods: <ul style="list-style-type: none"> <li>→ Based on exposure status</li> <li>→ OR based on factor other than exposure e.g. geographic location.</li> </ul> </li> </ul> </li> <li>03. Measure the exposure.</li> <li>04. Follow up at intervals to get accurate outcome data.</li> <li>05. Analyze data.</li> </ol>	<b>Analysis in cohort studies:</b>	<p>The data are analyzed in terms of:</p> <ol style="list-style-type: none"> <li>1. Incidence (rates of outcome among exposed and non-exposed. 2. Estimation of risk: <ul style="list-style-type: none"> <li>→ Relative Risk (also known as Risk Ratio) (RR).</li> <li>→ Attributable Risk (AR).</li> </ul> </li> </ol>
-----------------------------	--	------------------------------------	---

<b>Measuring Exposure</b>	<ul style="list-style-type: none"> <li>◦ <b>Levels of exposure</b> (e.g. packs of cigarettes smoked per year) are measured for <u>each individual</u> at: <ol style="list-style-type: none"> <li>1-Baseline at the <b>beginning</b> of the study.</li> <li>2. Assessed at intervals <b>during the period of follow-up</b>.</li> </ol> </li> <li>◦ A particular problem occurring in cohort studies is whether <u>individuals in the control group</u> are truly unexposed. <b>For example</b>, study participants may start smoking or they may fail to correctly recall past exposure. Similarly, those in <u>the exposed group</u> may change their behaviour in relation to the <u>exposure</u> such as diet, smoking or alcohol consumption.</li> <li>◦ <b>Sources for Exposure data:</b> medical or employment records, standardized questionnaires, interviews and by physical examination.</li> </ul>
---------------------------	--

<b>Measuring Outcome</b>	<ul style="list-style-type: none"> <li>◦ <b>Sources for outcome data:</b> <ul style="list-style-type: none"> <li>- routine surveillance of cancer registry data, death certificates, medical records or directly from the participant.</li> </ul> </li> <li>◦ Method used to ascertain outcome must be <b>identical for both</b> exposed and unexposed groups.</li> </ul>
--------------------------	---

<b>Issues:</b>	<ol style="list-style-type: none"> <li><b>1-Loss to Follow Up</b> (members may die, migrate, change jobs or withdraw from the study. In addition, losses to follow-up may be related to the exposure, outcome or both which can lead to biases.)</li> <li><b>2-Differential Misclassification of Subjects</b> (A major source of potential bias in cohort studies arises from the degree of accuracy with which subjects have been classified with respect to their exposure or disease status.+Differential misclassification can lead to an over or underestimate of the effect between exposure and outcome)</li> <li><b>3-Selection Bias</b> (however is cohort occurs :<b>1.Outcome ascertainment differs between exposed and unexposed. 2. Healthy worker effect</b>)</li> <li><b>4-Confounding</b></li> </ol>
----------------	--

<b>Strengths</b>	<b>Weaknesses</b>
<ul style="list-style-type: none"> <li>• Multiple outcomes can be measured for any one exposure.</li> <li>• Can look at <b>multiple outcomes</b>.</li> <li>• <b>Exposure is measured before the onset of disease</b> (in prospective cohort studies).</li> <li>• <b>Good for measuring rare exposures</b>.</li> <li>• Demonstrate causality.</li> <li>• <b>Can measure incidence</b>.</li> </ul>	<ul style="list-style-type: none"> <li>• Costly and time consuming.</li> <li>• <b>Prone to bias due to loss to follow-up</b>.</li> <li>• Prone to confounding.</li> <li>• Participants may move between one exposure category.</li> <li>• Knowledge of exposure status may bias classification of the outcome.</li> <li>• Being in the study may alter participant's behavior.</li> <li>• Poor choice for the study of a rare disease (<b>rare outcome</b>).</li> <li>• Classification of individuals (exposure or outcome status) can be affected by changes in diagnostic procedures</li> </ul>

# L12 Experimental Study Design

Definitions	Randomized controlled trial	<p>Individuals are <b>allocated at random</b> to receive one of several interventions (at least two total)</p> <p>RCT= Experimental Interventions= controlled by the investigations</p>	
	Random allocation	<p>All participants have a <b>defined probability</b> of assignment to a particular intervention</p> <ul style="list-style-type: none"> <li>- Allocation is <b>NOT</b> determined by the investigator, clinicians, or participants</li> <li>- Allocation is <b>NOT</b> predictable based on a pattern</li> </ul>	
	Experimental study	<p>Something is given or done to the experimental group but not to the control group and the resulting differences in the outcome are compared.</p>	
There is <b>NO</b> best type of study design. Choosing the study design should depend on:		<ol style="list-style-type: none"> <li>1. <b>Research questions and objective</b></li> <li>2. The knowledge already available about the problem</li> <li>3. Available resources (cost, time, expertise of the researcher)</li> <li>4. Ethics</li> </ol>	
What purpose is served by random allocation?		<ul style="list-style-type: none"> <li>- Covariates are distributed equally across the groups at baseline</li> <li>- Affects both measured and, more importantly, unmeasured variables</li> </ul>	
Methods of Randomization		<ul style="list-style-type: none"> <li>- Date of birth (odd to group 1; even to group 2)</li> <li>- Hospital record number (last digit; odd to group 1, even to group 2)</li> <li>- Day of enrollment (Monday=Rx, Tues=Placebo, etc)</li> <li>- Alternating (first person=Rx, second person=placebo, etc)</li> </ul>	
What elements of a trial can be randomized?		<ul style="list-style-type: none"> <li>- <b>Individual patient</b> (Most common)</li> <li>- Cluster randomization = groups are randomized (worry about contamination <b>كل</b> لأنها مجموعة كبيرة فلو مثلا قلنا راح نشوف تأثير الاكل الصحي على الطلبة في المدراس ماراح نقدر نتأكد ان كل طالب اتبع نظام صحي فهذا بيأثر بالنتائج ) Ex: families, schools, towns, hospitals, communities Special statistical techniques needed to cope with the loss of independence of the individual units</li> </ul>	
<b>How is randomization achieved? Two steps involved:</b>			
1-Generation of allocation sequence	Simple randomization	Analogous to a repeated fair coin tossing	
	Restricted randomization (Blocking)	<ul style="list-style-type: none"> <li>- Done to ensure equal balance of arms throughout all portions of the study.</li> <li>- For example, blocks of six would have 3 active/3 control.</li> <li>- Block size itself can/should vary (الفكرة هي كل بلوك يمثل مجموعة تقسمها عشوائيا فيكون عندك مثلا ست قروب واحد تدخلهم الاكمل ويزعم عشوائي) (طالب اتبع نظام صحي فهذا بيأثر بالنتائج ) ( وقروب اثنين وهكذا )</li> </ul>	
	Stratified randomization	<p>Individuals are identified based on important covariates (sex, age, etc.) and then randomization occurs within the strata (مثال الدكتوراة قالت لو كان عندك دراسة وعينتها طلبة الطب من ١-٥ فتشبه البلوك بانك بيكون عندك مجموعة من كل سنة وتوزعهم عشوائي الفرق بينه وبين البلوك انه هنا كل قروب مشترك بصفة معينة)</p>	
2-Implementation of allocation (concealment of allocation)	Concealment of allocation	<ul style="list-style-type: none"> <li>- <b>Concealing the allocation sequence</b> from those assigning participants to the intervention groups, until the moment of assignment → it prevents researchers from (unconsciously or otherwise) influencing which participants are assigned to the intervention or control group.</li> <li>- If those making the decision about patient eligibility are aware of the arm of the study to which the patient will be allocated (if randomization is unconcealed) they may systematically enroll sicker or less sick patients to either treatment or control groups. This will defeat the purpose of randomization and the study will yield a <b>biased result</b>.</li> </ul>	
	Blinding (Masking)	<ul style="list-style-type: none"> <li>- Procedure to protect the randomization process <b>before</b> the subject enters the trial</li> <li>- Concealment of allocation is <b>ALWAYS</b> feasible</li> <li>- If not done, results in <b>selection bias</b> (randomization benefits are lost, and treatment assignment is no longer truly random)</li> </ul>	
Strengths		<ul style="list-style-type: none"> <li>- One treatment is directly compared to another to establish superiority.</li> <li>- This study design can make causal inferences, i.e. it is the strongest empirical evidence of a treatment's efficacy</li> <li>- Minimum bias</li> </ul>	
Limitations		<ul style="list-style-type: none"> <li>- Resource, expensive</li> <li>- Results may not mimic real life application</li> <li>- Ethical implications: denying treatment to one group, ability to provide informed consent</li> </ul>	
Extra info but important		<ul style="list-style-type: none"> <li>- <b>Characteristic of an experimental study: Assignment of intervention</b></li> <li>- <b>Experimental studies is designed to use when you are interested in modifying exposures</b></li> <li>- <b>Experimental studies requires prospective data</b></li> <li>- <b>Random assignment is the technique used to control both known and unknown independent variables</b></li> <li>- <b>Examples on experimental studies: new vaccine and old vaccine comparison, comparing drugs effects between two groups</b></li> </ul>	

# L13 Qualitative Research

<p>What is qualitative research?</p>	<p>A strategy for <b>systematic collection, organization and interpretation of textual information.</b>          Answers <b>how and why</b> a certain phenomenon occurs and Uses inductive approach to generate novel insights into phenomena</p>				
<p>Why qualitative?</p>	<ul style="list-style-type: none"> <li>• Focuses on lived experience</li> <li>• Preserves chronological flow</li> <li>• Makes sense of incongruent data</li> <li>• Rich and holistic</li> <li>• Compliments quantitative data</li> </ul>	<p><b>How might you collect data for a qualitative study</b></p>	<p><b>1-Interviews</b> : Structured , Semi structured ,Unstructured  <b>2-Focus groups:</b>Why do a focus group? Little is known about a topic , At the early stages of a research project , Mixed methods  <b>3-Observation:</b>Researcher observes participants in natural environments</p>		
<p>When to use qualitative research?</p>	<ul style="list-style-type: none"> <li>• Exploring a health problem or issue about which little is known</li> <li>• Produce conceptual models</li> <li>• Investigating the feasibility, acceptability and appropriateness of potential programmes.</li> <li>• Identifying problems in on-going interventions and suggesting appropriate solutions to those problems</li> <li>• Can help in identifying cultural and social factors that affect health care positively or negatively.</li> <li>• Complementing quantitatively collected data by helping to interpret its results.</li> <li>• Designing more valid survey instruments.</li> </ul>				
<p><b>Qualitative approaches</b></p>	<ul style="list-style-type: none"> <li>• Phenomenology • Grounded theory</li> <li>• Ethnography • Case study</li> </ul>	<p><b>Examples of Qualitative Research Methods</b></p>	<ul style="list-style-type: none"> <li>• Focus group discussion</li> <li>• Key informant interviews</li> <li>• Ethnography</li> <li>• Phenomenology</li> </ul>		
<p><b>Comparing Approaches</b></p>	<p style="text-align: center;"><b>Qualitative</b></p>		<p style="text-align: center;"><b>Quantitative</b></p>		
	<p><b>Approaches 1</b></p> <ul style="list-style-type: none"> <li>• Understanding</li> <li>• Interview/observation</li> <li>• Discovering frameworks</li> <li>• Text( words ) , images , objects</li> <li>• Theory generating</li> <li>• Quality of informant more important than sample size</li> <li>• Subjective</li> <li>• Embedded knowledge</li> <li>• Models of analysis: fidelity to text or words of interviewees</li> </ul>	<p><b>Approaches 2 Methods</b></p> <ul style="list-style-type: none"> <li>• Focus Groups</li> <li>• Interviews</li> <li>• Surveys</li> <li>• Self-reports</li> <li>• Observations</li> <li>• Document analysis</li> <li>• Sampling: Purposive</li> </ul>	<p><b>Approaches 1</b></p> <ul style="list-style-type: none"> <li>• Prediction</li> <li>• Survey Questionnaires</li> <li>• Existing frameworks</li> <li>• Numerical</li> <li>• Theory testing (experimental)</li> <li>• Sample size core issue in reliability of data</li> <li>• Objective</li> <li>• Public Model of analysis: parametric, non-parametric</li> </ul>	<p><b>Approaches 2 Methods</b></p> <ul style="list-style-type: none"> <li>• Observational</li> <li>• Experimental</li> <li>• Mixed</li> <li>• Sampling: Random (simple, stratified, cluster, etc) or purposive</li> </ul>	
<p><b>Characteristics of Qualitative Research</b></p>	<ul style="list-style-type: none"> <li>• Purpose is understanding meanings people have constructed.</li> <li>• Uses subjective data.</li> <li>• The researcher is the instrument.</li> <li>• Deals with local conditions not controlled</li> <li>• “Naturalistic”</li> <li>• Interpret results in contexts</li> <li>• The researcher’s signature is apparent</li> </ul>				
<p><b>Qualitative Research Techniques</b></p>	<p>Interviews /Focus groups          Observation          Content analysis/Video or Text and Image analysis</p>	<p><b>Involves Skills of</b></p>	<ul style="list-style-type: none"> <li>• Observing</li> <li>• Conversing</li> <li>• Participating</li> <li>• Interpreting</li> </ul>	<p><b>Sampling in Qualitative research :</b></p>	<p>1-Types of sampling e.g. purposive, snowballing...          2-Collect data <b>until data saturation</b></p>
<p><b>How might you collect data for a qualitative study:</b></p>	<p><b>1-Interviews:</b></p> <ol style="list-style-type: none"> <li>1. Structured</li> <li>2. Semi-structured</li> <li>3. Unstructured</li> </ol>	<p><b>2 -Focus groups</b></p>	<p>Why do a focus group?</p> <ul style="list-style-type: none"> <li>• Little is known about a topic</li> <li>• At the early stages of a research project</li> <li>• Mixed methods</li> </ul>	<p><b>3 -Observation</b></p>	<p>Researcher observes participants in natural environments</p>

Consider these questions  
 • Why do people smoke ? • Why do people eat what they eat ? • Why don't most people in our part of the world exercise ? • How do people contract infection ? • How is such information useful ?

# L13 Qualitative Research

## Qualitative Methodologies (Example) :

An ethnography is a description and **interpretation of a cultural or social group or system**. The research examines the group's observable and learned patterns of behaviour, customs, and ways of life

Phenomenology is the study of **human experience** and of the ways things present themselves to us in and through such experience -the study of structures of consciousness as experienced from the first-person point of view.

The main difference between ethnography and phenomenology is that **ethnography** focuses **on the collective experiences of a community** whereas **phenomenology** focuses on the individual **experiences of individuals**.

## Data Analysis Steps :

- Organize and prepare the data for analysis
- Read all data, get a sense of the whole
- Begin detailed analysis with coding process
- Generate a description of the setting /people as well as categories or themes for analysis
- Represent themes (writing, visual, etc.)
- Interpret and make meaning out of data
- **iterative, non-linear process**

Analyzing data :

- Cut and past • Software programmes, e.g. NVivo, ATLAS.ti, NUD\*IST

## How can I reduce subjectivity in qualitative research :

- Reflectivity • Probing • Triangulation

## Concluding remarks

- Qualitative research identify what really matters for patients and care providers
- Qualitative methods can provide unique contributions to health services and clinical research
- There are widely accepted procedures for study design, sampling, data collection, and data analysis in qualitative research



# L14 Practical Session: Selection of Study Design

**Representative** sample of residents were telephoned and asked how much they exercise each week and whether they currently have (have ever been diagnosed with) heart disease. Exposure and Outcome BOTH measured at the SAME TIME at INDIVIDUAL level

## Cross-Sectional

To determine the risk factors for hip fractures in post menopausal women (e.g. osteoporosis, obesity, hip Injury, and physical inactivity) (multiple exposures - single outcome)

## Case control

To evaluate the association between use of group of medicinal drugs (benzodiazepines) used for treating anxiety and /or insomnia in adults and **incidence** of dementia. ( incidence , single exposure )

## Prospective Cohort

**Investigating** that caesarean-section delivery may reduce the risk of mother-to-child transmission of HIV infection in comparison with vaginal delivery.

## Experimental/clinical trial

In-charge of social organization wants to study emotional trauma in social workers who work with battered women. She has a validated scale/tool that can assess emotional trauma in workers. You are consulted; explain how will you design the study?

## Cross-Sectional

What is the **prevalence** of hypertension in adults > 30 years of age living in Riyadh Central Region?

## Cross-Sectional

Occurrence of cancer was identified between April 1991 and July 2002 for 50,000 troops who served in the first Gulf War (ended April 1991) and 50,000 troops who served elsewhere during the same period. (incidence . Observe , past 'retrospective)

## Cohort study

Football coach has observed that recently the number of disabling injuries on the field has increased compared to previously. He is suspicious and wants to investigate what medicinal/nutritional supplements are being used by the players during the past three months. He discusses this with a sports physician who examines all injuries occurring on the field. How can you help him design a study? (incidence . Observe , past 'retrospective)

## Retrospective Cohort

A population-based study determined whether there is a **relationship** between childhood asthma and environmental exposure to secondhand smoke. A sample of the population was interviewed to gather information about asthma symptoms and some environmental exposures in 2003.

## Cross-Sectional

You are working in a TB center. You want to describe the characteristics and contact history of cases with drug resistant TB. How will you design the study?

## Case Series

Subjects were children enrolled in a health maintenance organization. At 2 months, each child was **randomly** given one of two types of a new vaccine against rotavirus infection. Parents were called by a nurse two weeks later and asked whether the children had experienced any of a list of side-effects.

## Experimental study

# from doctor: Selection of Study Design

**“Primary spontaneous pneumothorax is a common disorder occurring in young adults without underlying lung disease. Although tobacco smoking is a well- documented risk factor for spontaneous pneumothorax, an association between electronic cigarette use (that is, vaping) and spontaneous pneumothorax has not been noted. We report a case of spontaneous pneumothoraces correlated with vaping”**

## **Descriptive – Case Report**

**“Fourteen patients were treated for electronic cigarette burns between 2012 and 2016. Burn size ranged from <1% to 6% total body surface area. Most patients suffered burns to their thighs because the battery or device exploded in their pocket. The majority suffered partial thickness burns while four patients had full thickness burns. Three patients required excision and autografting, all of which were full thickness burns. The average time to recovery was 24.5 days”**

## **Descriptive – Case Series**

“We conducted 12 focus groups and two individual interviews with young adult nonusers, e-cigarette vapers, cigarette smokers, and dual users to assess beliefs about the effects of e-cigarettes. After a series of open-ended questions, follow-up questions assessed reactions to domains previously examined in expectancy measures for cigarette smoking and e-cigarette vaping. The constant comparative method was used to derive themes from transcripts”

## **Study design: Descriptive – Qualitative**

“A survey of 6902 German students (mean age 13.1 years, 51.3% male) recruited in six German states was performed. Exposure to e-cigarette advertisements was measured with self-rated contact frequency to three advertising images. Multilevel mixed-effect logistic regression models were used to assess associations between exposure to e-cigarette advertisement and use of e-cigarettes, combustible cigarettes and hookahs.”

## **Spot the design! Three questions:**

**Q1: Analytical (association)**

**Q2: Observational (exposure was not randomly allocated)**

**Q3: Cross-sectional (Exposure & Outcome at the same time)**

“Adult smokers ( $\geq 18$  years old) making their first purchase at local participating vape shops were asked by professional retail staff to complete a form with their basic demographic and smoking history details together with scoring of their level of nicotine dependence by a questionnaire. Participants were instructed how to charge, fill, activate and use their e-cigs. Key troubleshooting was addressed and phone numbers were supplied for technical assistance. Participants were encouraged to use these products in the anticipation of reducing the number of cig/day smoked. Their cigarette consumption was followed-up at 6 and 12 months”

**Q1: Analytical (association)**

**Q2: Observational (exposure was not randomly allocated)**

**Q3: Cohort study (Exposure is measured BEFORE Outcome is measured)**

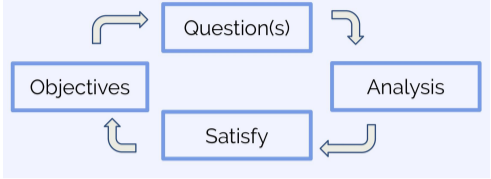
**“We randomly assigned adults attending U.K. National Health Service stop- smoking services to either nicotine-replacement products of their choice or an e- cigarette starter pack with a recommendation to purchase further e-liquids of the flavor and strength of their choice. Treatment included weekly behavioral support for at least 4 weeks. The primary outcome was sustained abstinence for 1 year, which was validated biochemically at the final visit”**

**Q1 Analytical (association)**

**Q2: Experimental (exposure was randomly allocated) - RCT**

**Q3: Not Applicable**

# L15 Tools for data collection: Using Questionnaire & other tools

<p><b>Step to design a Questionnaire</b> Each step will be discussed below</p>	<p>1-write the primary + sec. Aims 2-write out concept/information (that relates to these aims) <b>3-review the current literature</b> to identify already validated questionnaires that measures your specific area of interest. <b>Very important; To confirm that what are you doing is validated, authentic and has not been done.</b> 4-Compose a draft.    5-Revise the draft    6-assemble the final questionnaire</p>
<p>1- Define the aims of the study:  <b>IMPORTANT</b></p>	<ul style="list-style-type: none"> <li>● <b>one sentence per aim.</b></li> <li>● <b>Formulate a plan for the statistical analysis of each aim.</b></li> </ul> 
<p>2- Define the variables to be collected:</p>	<ol style="list-style-type: none"> <li>1. A detailed list of the <b>information</b> to be collected: KAP, Needs, Risk factors, behavior, diet, habit, demographics and associations (gender, age)</li> <li>2. <b>Translate into variables</b> that can be <u>measured</u>.</li> <li>3. Define the <b>role of each variable</b> in the statistical <u>analysis</u>: -Predictor (independent).    -Outcome (dependent).    -Confounder and/or effect modifier.</li> </ol>
<p>3-Review the literature:</p>	<p>نباحتصار نراجع البحوث السابقة التي تشابهنا فنعرف كيف قاسو الداتا، فلو نبحت عن كمية المصابين بالإكتئاب نشوف البحوث السابقة وش استخدمت</p> <p>Review <b>current literature</b> to identify related <b>surveys</b> and <b>data collection</b> instruments that have measured aims similar to your aims.</p> <p><b>You may get:</b></p> <ul style="list-style-type: none"> <li>● Validated questionnaires &gt; so you save your time</li> <li>● Detailed items</li> <li>● Comparison of result.</li> </ul>
<p>4- Compose the file draft:</p>	<ul style="list-style-type: none"> <li>● Determine the <b>mode of survey administration</b>: هنا نحدد كيف بنجمع الداتا 1-Face-to-face interview.    2-Self-administered survey (i.e. mail survey). 3-Telephone survey.    4-E-mail survey. هذي النقطة مهمة لأن بعض العينات أنسب لها طرق معينة، فالجامعات مثلاً يناسبها الأيميلات وهكذا</li> <li>● <b>Add more questions</b> than will be included in the <b>final draft</b>.</li> <li>● <b>Longer questionnaires reduce the response rate.</b></li> <li>● <b>Place the most important items in the first half of the questionnaire.</b> <b>The most important questions at the start, and sensitive questions at the end.</b></li> <li>● Make sure questions flow naturally from one to another. <b>This is a very common mistake.</b></li> <li>● Include <b>identifying data</b> on <b>each page</b> of multipage, paper page questionnaires. Such as respondent ID number in case the pages separate.</li> <li>● At the top of the questionnaire: 1-Introduce yourself briefly. <b>And informed consent.</b>    2-The purpose of the study. 3-How will the data be used.    4-your policy on confidentiality. 5- Instructions on how to fill out the questionnaire and how long will it take to fill it. <b>All these factors will increase your response rate. What response rate is acceptable? 80-85%</b></li> </ul>
<p>5- Revise</p>	<p>-shorten the set of questions (+ if a Question doesn't address one of the aims,remove it) <b>-Refine the Qs</b> included their wording (<b>test your question with a variety of respondents</b>) and ensure that:</p> <ul style="list-style-type: none"> <li>● <u>Flow is natural</u></li> <li>● Terms and concepts are <u>familiar</u> and <u>easy</u> to understand</li> <li>● Keep recall to minimum + focus on the recent past.</li> </ul>
<p>6- Assemble the final questionnaire:</p>	<ul style="list-style-type: none"> <li>● Group Questions concerning major subject areas together and introduce them by heading or short descriptive statemen. نسوي هيدنق للأسئلة التي لها علاقة بالمواضيع الأساسية</li> <li>● list questions in order to <b>stimulate recall</b>.</li> <li>● Order and format questions to ensure <b>unbiased and balanced</b> results.</li> <li>● Place the most <b>important</b> items in the <b>first half of the questionnaire</b>.</li> <li>● Make sure questions <b>flow naturally</b> from one to another.</li> </ul>

# L15 Tools for data collection: Using Questionnaire & other tools

## Testing the Survey instrument, Include:

- Focus groups discussions.
- Cognitive interviews.
- field pre-testing. يعني قبل ما نرسل الاستبيان الحقيقي نرسل تجربة لعدد بسيط.

## Field pre-testing provide:

-Small-scale study in which all the **conditions** of the **full scale-survey** are simulated.

-survey modes. -interviewer oral debriefing and written reports.

## Field pre-testing warning sings:

-Variations (skewed distribution). -Response rate. - No opinion or (Dont know) rate. -Response Patterns. -flow of the questionnaires

## Qualities of the Questions

The <b>number of questions</b> should be determined in <b>relevance</b> to the <b>proposed objectives</b> .	Avoid sensitive and very personal questions, however, if the topic is of such a nature, leave them to the end.
Avoid irrelevant questions.	Avoid leading questions.
Use local language of community.	Arrange questions in an orderly manner.
Questions relating to the same issue should be kept together.	Avoid technical terms.
The questions must be simple, short, inquire about one thing at a time.	

## Questions and its correction

Incorrect Question	Principle	Solution
<b>How many cups of coffee or tea do you drink in a day?</b>	Ask for an answer in <b>only one dimension</b> .	<b>Separate</b> the question into two. مرة تسأل عن الشاهي ومرة عن القهوة <b>Edited choices:</b> -How many cups of coffee do you drink during a usual day? -How many cups of tea do you drink during a usual day?
<b>What brand of computer do you own?</b> -IBM PC -Apple	Avoid hidden assumptions. Make sure to accommodate all possible answers.	<b>-Make each response a separate dichotomous (ثنائية التفرع) item.</b> <b>Edited choices:</b> a. do you own an IBM PC? Yes or no. (circle) b. Do you own an Apple computer? Yes or no. (circle) <b>-Add all possible response categories and allow for multiple responses. You put on the most commonly used and others then leave a blank.</b> <b>Edited choices:</b> What brand of computer do you own? (Do not own computer, IBM PC, Apple, Oth with specifying). (circle)
<b>Have you had pain in the last week?</b> -never. -seldom. -often. -very often	Make sure question and answer options match.	<b>Reword either question or answer to match.</b> <b>Edited question:</b> How often have you had pain in the last week?
Survey given to teenagers. <b>Where did you grow up as a child?</b> <input type="checkbox"/> Country. <input type="checkbox"/> Farm. <input type="checkbox"/> City	Avoid questions having non-mutually exclusive answers.	Design the question with mutually exclusive options (they do not overlap each other). <b>Edited choices:</b> Where did you grow up as a child? <input type="checkbox"/> House in the countryside. <input type="checkbox"/> Farm house in the countryside. <input type="checkbox"/> Large city neighborhood. <input type="checkbox"/> Small town semi urban/rural. <input type="checkbox"/> Other with specifying.
Which one of the following do you think increases a person's chance of having a heart attack the most? -smoking -being overweight -stress	Encourage the respondent to consider each possible response to avoid the uncertainty of whether a missing item may represent either an answer that does not apply or an overlooked item.	Which of the following increases the chance of having a heart attack? <b>Edited choices:</b> <input type="checkbox"/> Smoking: YES, NO, DON'T KNOW. <input type="checkbox"/> Being overweight: YES, NO, DON'T KNOW. <input type="checkbox"/> Stress: YES, NO, DON'T KNOW.
Do you currently have a life insurance policy? Yes or No. (circle) 2. If no, How much is your annual life insurance premium?	Avoid branching as much as possible to avoid confusing respondent.	If possible, write as one question. <b>Edited question:</b> How much did you spend last year for life insurance? (Write 0 if none).

There are other questions in the slides

# L15 Tools for data collection: Using Questionnaire & other tools

## Some common mistakes:

### Main Mistakes (Q1)

1. Personal information, such as income, should always be kept until the end of the interview
2. Use of pre-coded income categories

For continuous variables like age, height, weight, etc. avoid using pre-coded options

### Main Mistakes (Q2)

Use simple, clear language

### Main Mistakes (Q3)

Avoid asking “aided awareness” questions. Keep questions short

### Main Mistakes (Q4)

Don't ask two different questions and give one response category Divide into two questions

### Main Mistakes (Q5)

Use skip pattern if necessary

.Q.4 Are you currently a member of a gym or fitness club?

1.Yes

2.No -----> Go to Question 6

Q.5 Please tell me what regular physical activity you participate in. \_\_\_\_\_

Open-Ended Question

### Main Mistakes (Q6)

Keep related questions together

Don't use abbreviations (PSA – public service announcement)

### Main Mistakes (Q7)

Don't ask two different questions and give one response category Use the same format for the whole questionnaire

### Main Mistakes (Q8)

Use simple, common language

Record the “action” in a more objective, direct manner

### Main Mistakes (Q9)

Don't use leading questions Keep related questions together

### Main Mistakes (Q10)

The introduction tells that the information they give is confidential. Asking for personal information after ensuring confidentiality needs to be explained clearly, and the respondent reassured that their name will not be associated with their responses.

The best way to do so is to state why you are asking, and then give them the option to provide the information, otherwise it can lead to some hostility.

## Leaders



**Rania almutiri**



**Homoud algadib**

## The work **done by**

**Raina almutiri**

**Rayan jabaan**

**Shaden alobaid**

**Hessah Fahad**

**Shatha Aldhohair**

**Sarah Alqahtani**

**Samar almohammedi**

**Nourah Alklaib**

**Muneerah Alsadhan**

**Fatimah binmeather**

**Ghada aljedaie**

**Sarah AlQuwayz**

**Abdulaziz alomar**