

Introduction and Methods in medical research



Mohammed Zimmo
PhD
Al Azhar University

What characterizes research?

Searching for
knowledge

Using a scientific
method

Systematic approach

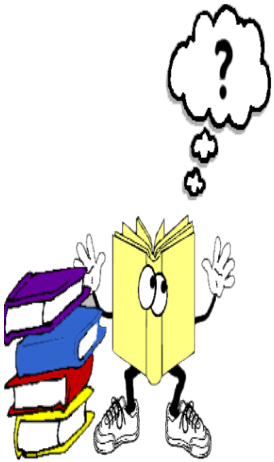
Detailed

documentation

Publication



Introduction to Research: General Concepts



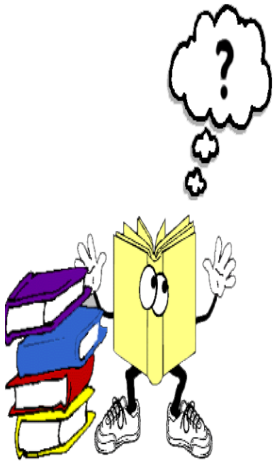
What is research?

Characteristics of the Scientific Method

Characteristics of Scientific Knowledge

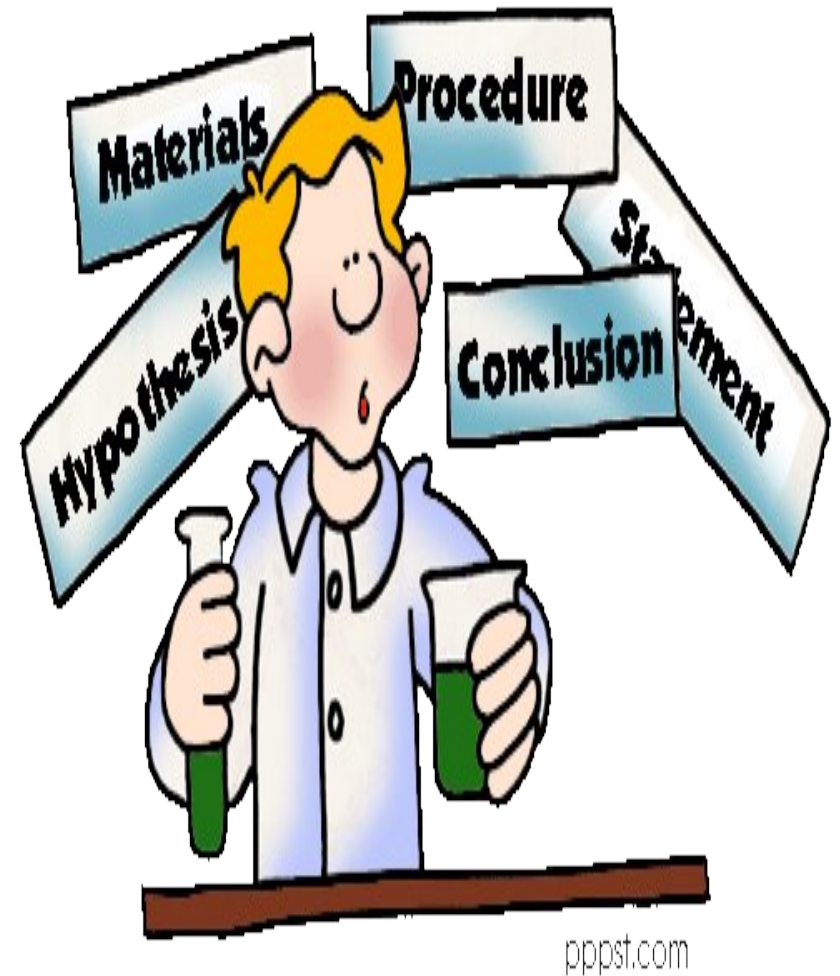
General Approaches to Research

Types of Research in Public Administration

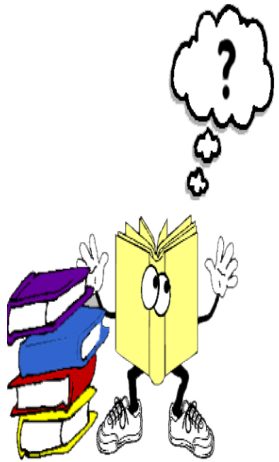


Research is an organized inquiry carried out to provide information for solving problems.

It is the cornerstone of every science.



What is research?



Re Searh



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Proce



SS

✓ Step by step
✓ Phases



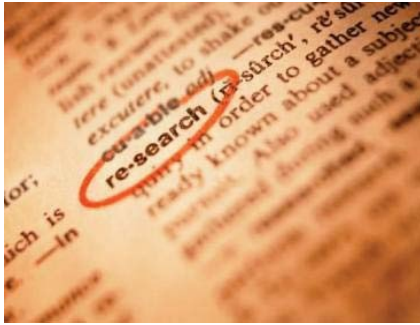
Wikipedia

Research can be defined to be

Search for knowledge

Or any systematic investigation to

establish facts



Research is

To see what **everybody else** has
seen

To think what **nobody else** has
thought

Albert Szent-Gyorgyi (1893 –
1986)





Research is

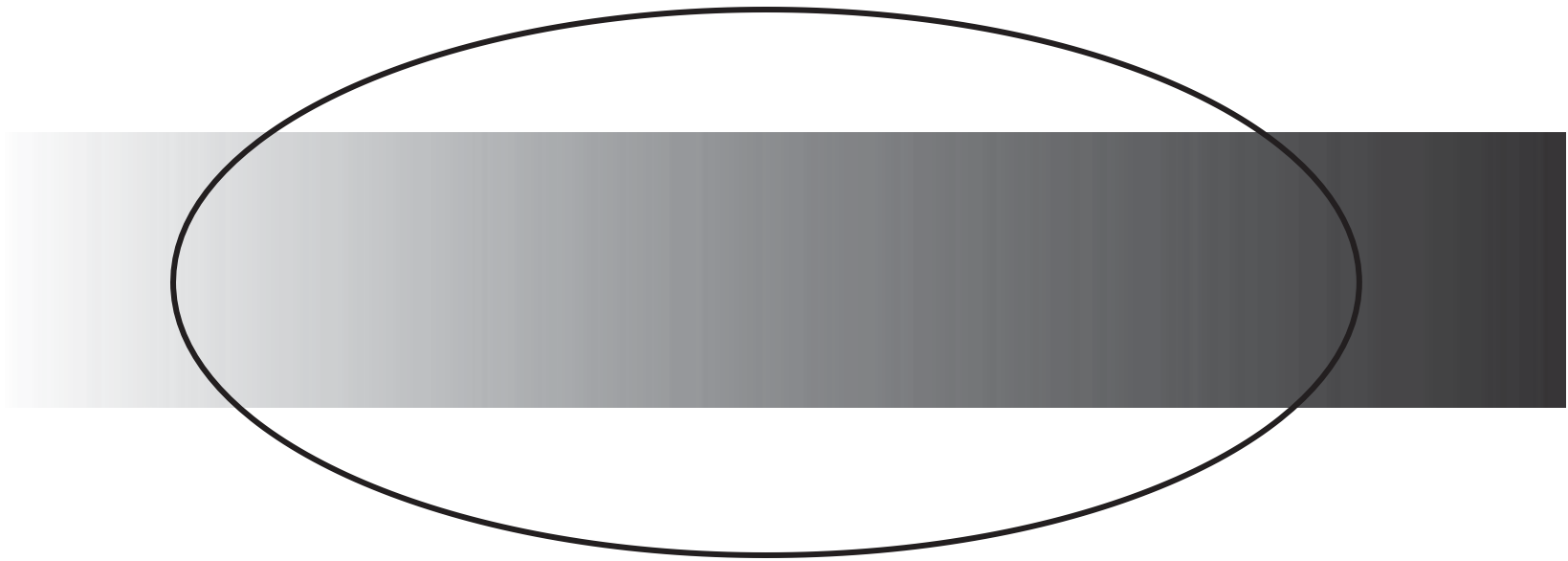
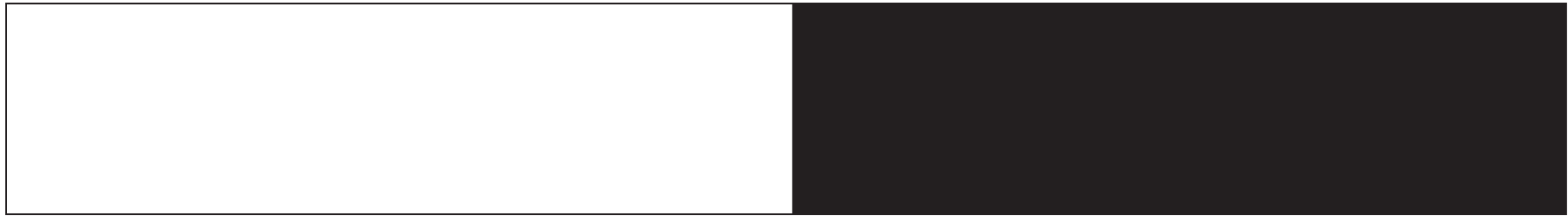
Research is the systematic process of collecting and analyzing information to increase our understanding of the world in general and of the phenomenon under study in particular.

Albert Szent-Gyorgyi (1893 – 1986)

Who conduct research?

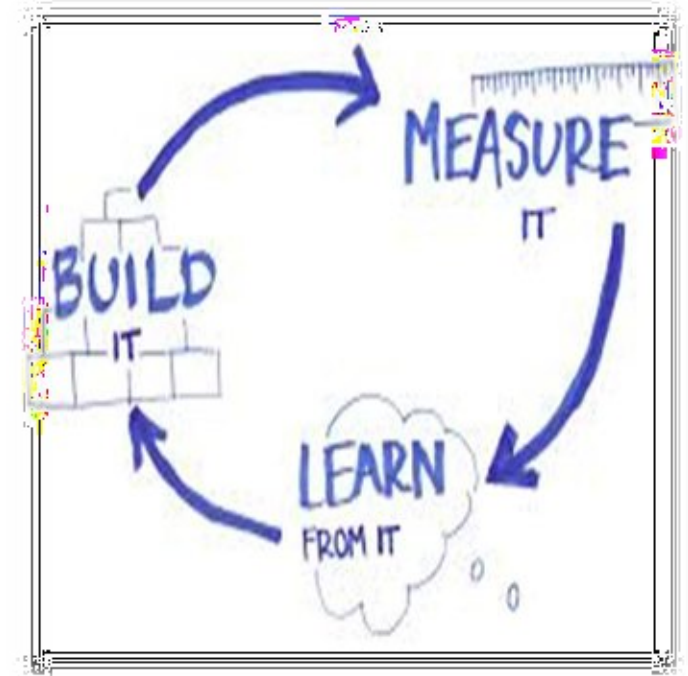
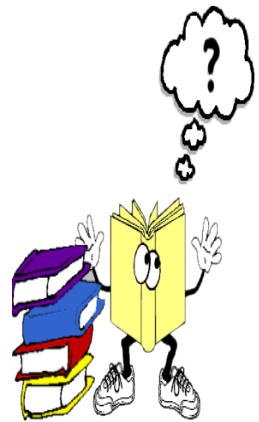
Students, professors, researchers, research centers, government, practitioners, newspaper people, TV networks, market research firms, schools, hospitals, social service, political parties, consulting firms, HR departments, public interest organizations, insurance, law firms conduct research as part of their jobs

Why conduct research?

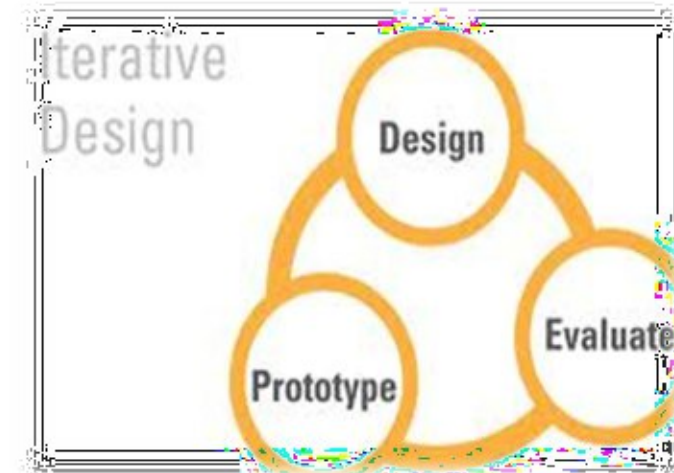


Why conduct research?

RESEARCH concerns with WHAT (facts and conclusions) and HOW (scientific; critical components).



Research is a iterative process that eventually seeks to explain



Research principles

Truth

Honesty

Transparency/complete openness

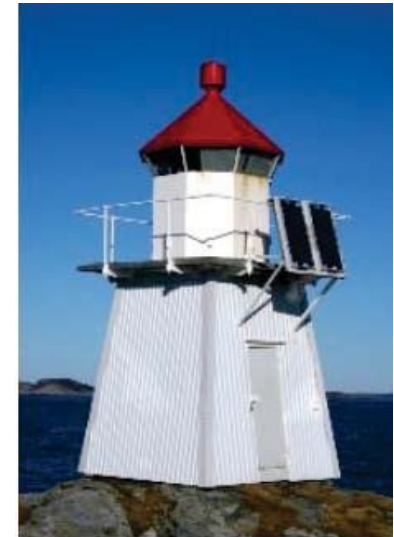
Systematic errors prevented by...

good design

Random errors corrected by...

statistical methods

Other “errors” are corrected over time
and by experience





**What is
medical
research
?**



Medical and health care research

Activities that are carried out with scientific methodology to provide new knowledge about health and disease



Research vs. health care



Research vs. health care

Health care:

Aims at producing health

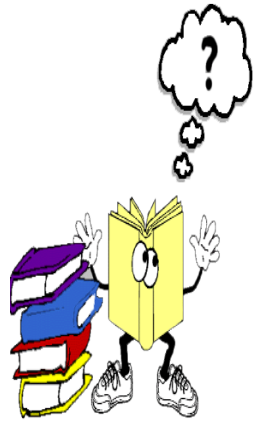


Research:

Aims at producing knowledge



Purpose of Research



explore
describe
e
explain

Differences between health research and health care

Aims

Funding

Documentation

Ethics

Legal
regulations

.....



Health Research Act

"The aim of this act is to promote good and ethical responsible medical research"



Legal requirements

Medical research should be organized as a project and have:

Responsible institution

Project leader

Protocol (in which all funding should be described)



Four basic principles for medical research

Safe and sound

Limits to what we are allowed to do, a general, superior principle

Board review

Approval from an independent body

Informed consent

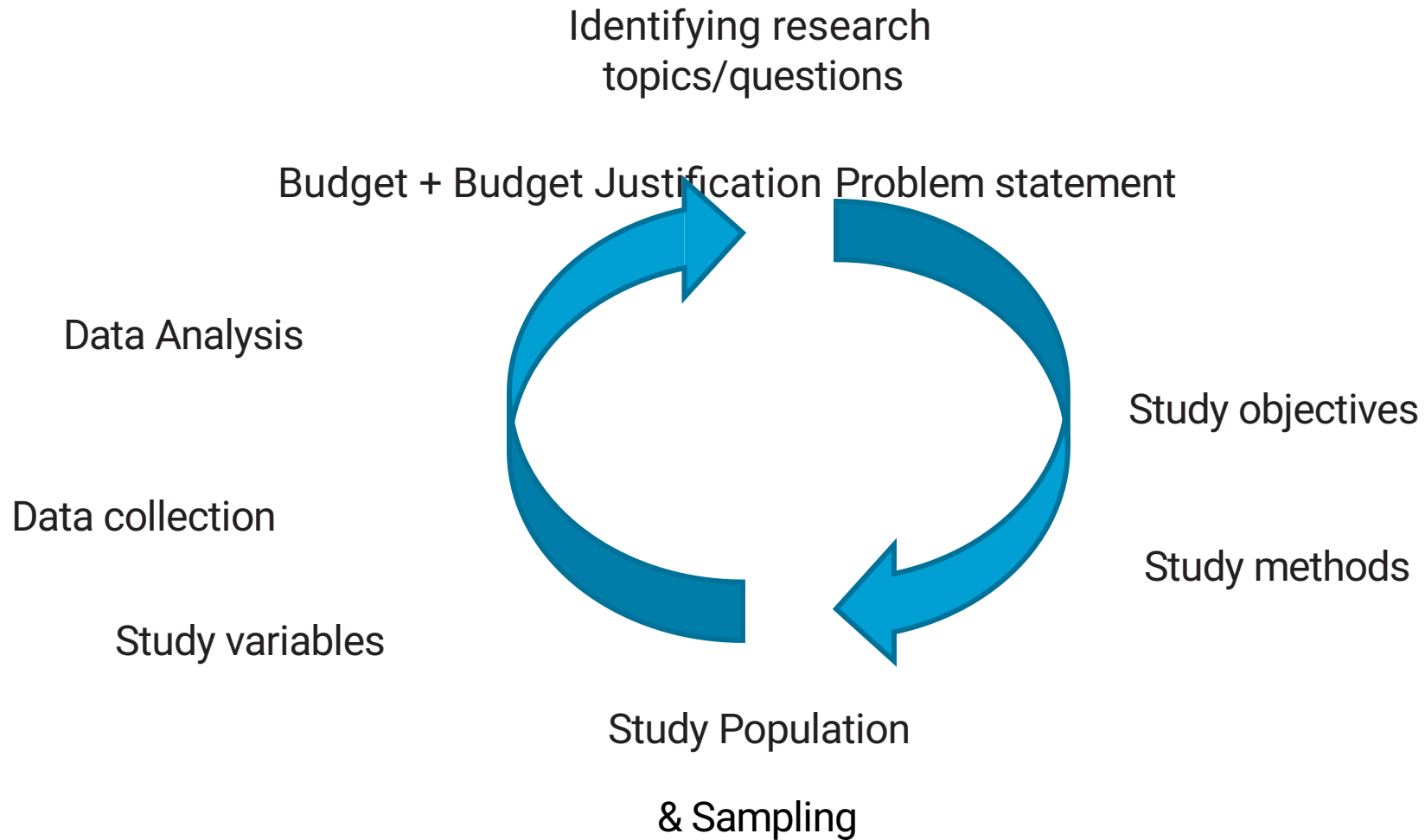
Autonomy

Proportionality

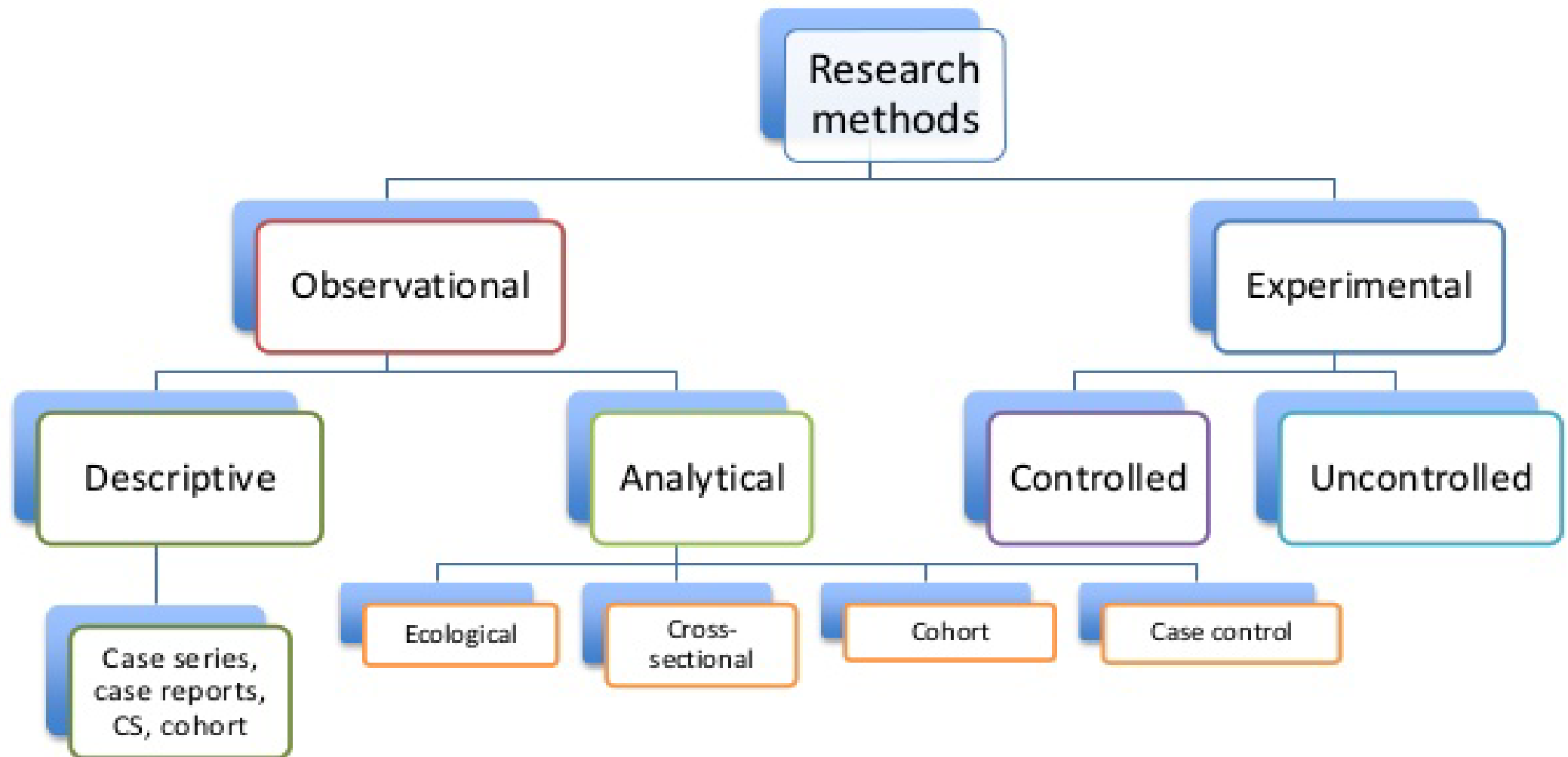
Acceptable risk, i.e. risks and burdens should be proportionate to potential benefits



Research Steps



Classification of research methods

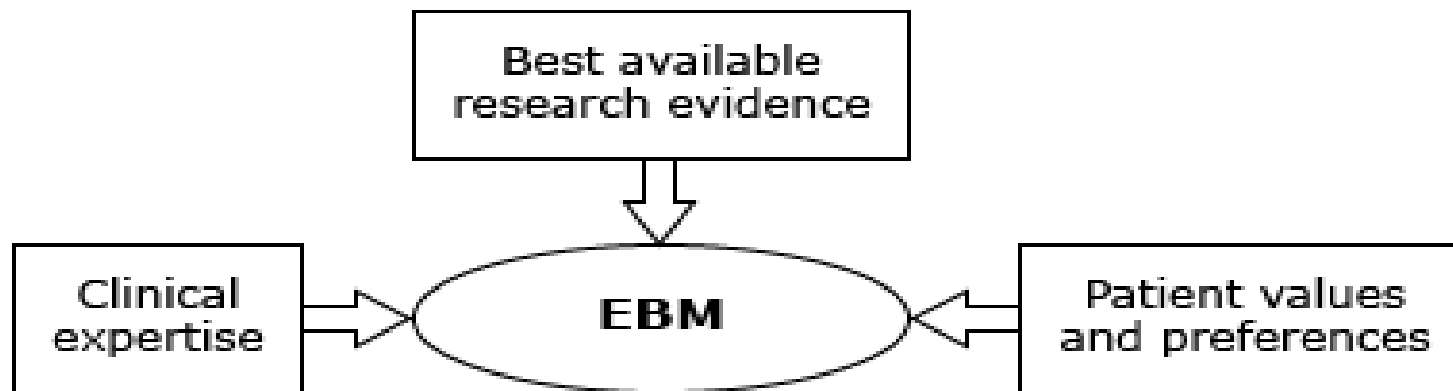


What is Evidence Based Medicine?



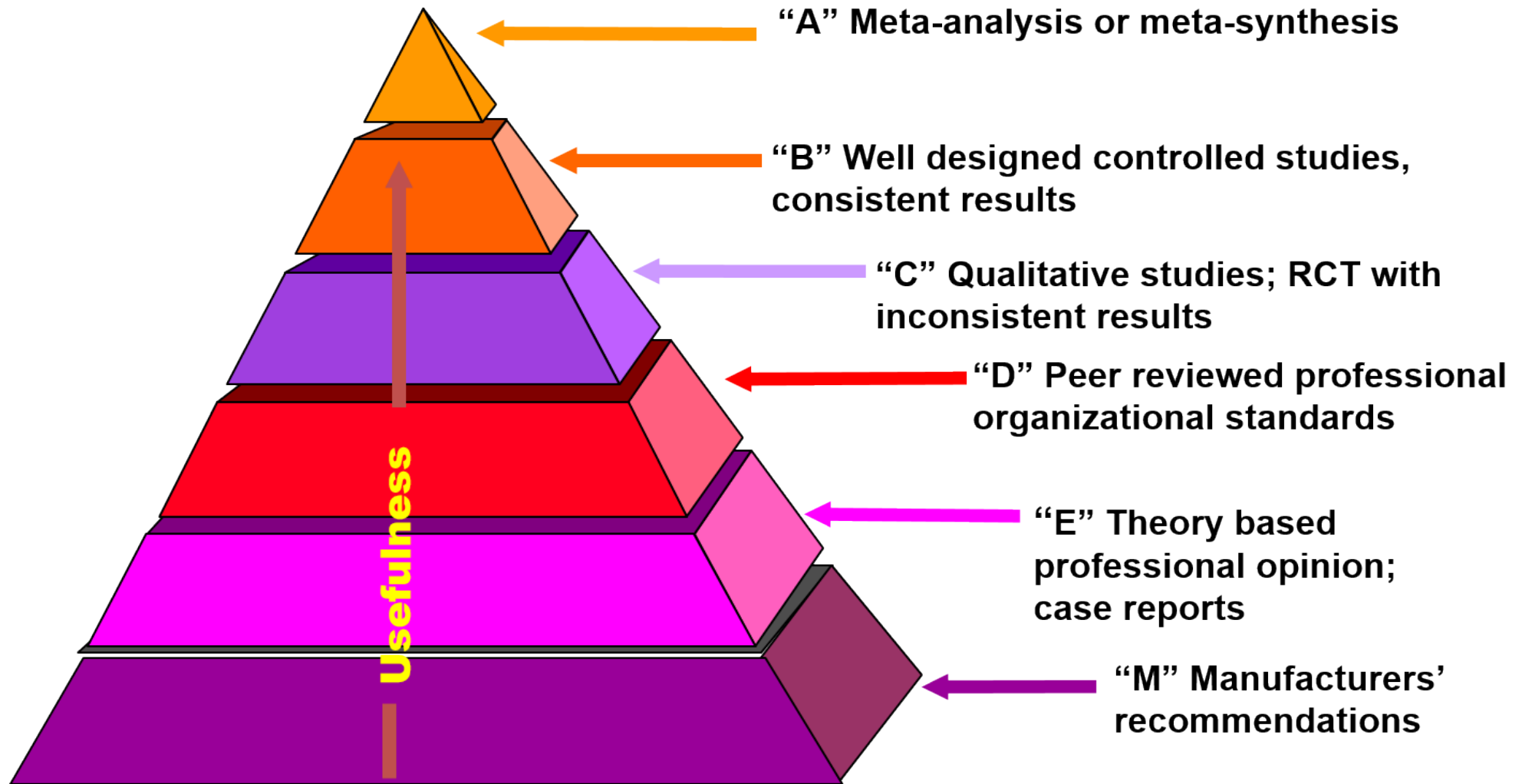
Evidence Based Medicine

Is the care of patients using the best available research evidence to guide clinical decision making



Sackett DL, Straus SE, Richardson WS, et al. Evidence-based medicine: How to practice and teach EBM, 2nd ed, Churchill Livingstone, Edinburgh.
Sackett DL, Rosenberg WM, Gray JA, et al. Evidence based medicine: what it is and what it isn't. BMJ 1996; 312:71.

Evidence Based Medicine



Evidence Based Medicine

Strength	Level	Design	Randomization	Control
High	Level 1	Randomized control trial (RCT)	Yes	Yes
		Meta-analysis of RCT with homogeneous results	No	
	Level 2	Prospective comparative study (therapeutic)	No	Yes
		Meta-analysis of Level 2 studies or Level 1 studies with inconsistent results	No	
	Level 3	Retrospective Cohort Study	No	Yes
		Case-control Study	No	Yes
		Meta-analysis of Level 3 studies	No	
	Level 4	Case Series	No	No
Low	Level 5	Case Report	No	No
		Expert Opinion	No	No
		Personal Observation	No	No

<https://www.hydroassoc.org/research-101-levels-of-evidence-in-hydrocephalus-clinical-research-stud>



Many ways of classifying tools – describe your methods!

A combination of different tools is frequently used

Research methods in epidemiology and clinical medicine

Knowledge
research

Descriptive
methods
description of
reality

Analytical
methods testing
one or more
hypotheses



Research methods in epidemiology and clinical medicine

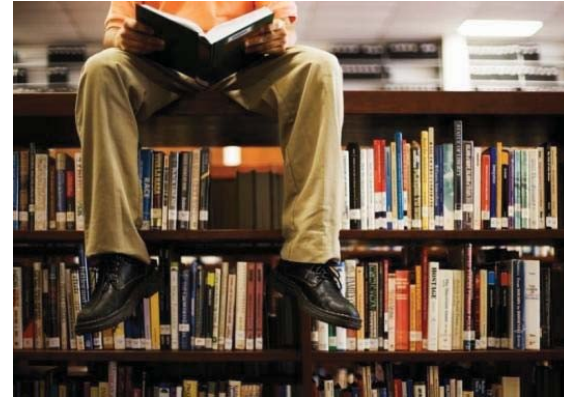
Knowledge research

Descriptive methods
description of reality

Analytical methods testing
one or more hypotheses



Knowledge research



Systematic reviews

A review of the literature on a single question that tries to identify, appraise, select and synthesize all high quality research evidence relevant to that question

Meta-analyses

Combines the results of several studies that address the same research question

Systematic assessment of existing research is always needed

Research: increasing value, reducing waste 1



How to increase value and reduce waste when research priorities are set

Iain Chalmers, Michael B Bracken, Ben Djulbegovic, Silvio Garattini, Jonathan Grant, A Metin Gülmezoglu, David W Howells, John P A Ioannidis, Sandy Oliver

The increase in annual global investment in biomedical research—reaching US\$240 billion in 2010—has resulted in important health dividends for patients and the public. However, much research does not lead to worthwhile achievements, partly because some studies are done to improve understanding of basic mechanisms that might not have relevance for human health. Additionally, good research ideas often do not yield the anticipated results. As long as the way in which these ideas are prioritised for research is transparent and warranted, these disappointments should not be deemed wasteful; they are simply an inevitable feature of the way science works. However, some sources of waste cannot be justified. In this report, we discuss how avoidable waste can be considered when research priorities are set. We have four recommendations. First, ways to improve the yield from basic research should be investigated. Second, the transparency of processes by which funders prioritise important uncertainties should be increased, making clear how they take account of the needs of potential users of research. **Third, investment in additional research should always be preceded by systematic assessment of existing evidence.** Fourth, sources of information about research that is in progress should be strengthened and developed and used by researchers. Research funders have primary responsibility for reductions in waste resulting from decisions about what research to do.

Introduction

This report will be focused on the waste of resources resulting from decisions about what research to do. After exploring investment patterns, we consider waste that ensues when the needs of potential users of research evidence (ie, policy makers, patients, professionals making practice or personal decisions, and researchers and research funders deciding which additional research should be done) are ignored and what is already known or already being researched is overlooked. We conclude with recommendations for how to reduce waste when research priorities are set.

We have approached our task using the research categories suggested by Stokes:¹ pure basic research (to advance knowledge), pure applied research (to increase immediate applicability of research results in practice and policy decisions), and use-inspired basic research (to both advance knowledge and increase applicability). Stokes created a schema to represent categories, which we have adapted (figure 1). He named the quadrant representing use-inspired basic research after Louis Pasteur, because Pasteur's basic research had been motivated by the need to generate evidence relevant to reductions in morbidity, mortality, and economic costs of infections in people and animals. In our adapted schema, we have retained Pasteur in his original quadrant, but replaced Nils Bohr (the nuclear physicist) with Marie Curie in the quadrant for pure basic research, because of

Recommendations

1. More research on research should be done to identify factors associated with successful replication of basic research and translation to application in health care, and how to achieve the most productive ratio of basic to applied research
 - Monitoring—periodic surveys of the distribution of funding for research and analyses of yields from basic research
2. Research funders should make information available about how they decide what research to support, and fund investigations of the effects of initiatives to engage potential users of research in research prioritisation
 - Monitoring—periodic surveys of information on research funders' websites about their principles and methods used to decide what research to support
3. Research funders and regulators should demand that proposals for additional primary research are justified by systematic reviews showing what is already known, and increase funding for the required syntheses of existing evidence
 - Monitoring—audit proposals for and reports of new primary research
4. Research funders and research regulators should strengthen and develop sources of information about research that is in progress, ensure that they are used by researchers, insist on publication of negative studies

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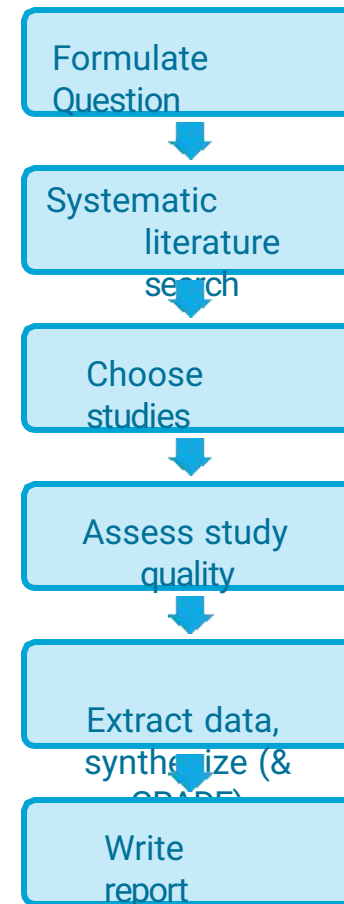
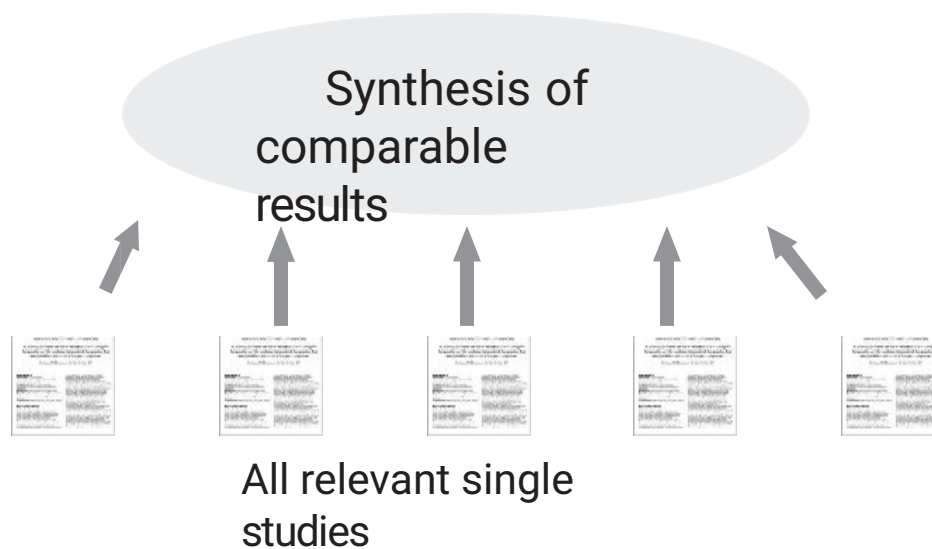
This is the first in a Series of five papers about research

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Systematic

P	I	C	O
Population Patient Problem	Intervention Or Exposure	Comparison	Outcome
Who are the patients? What is the problem?	What do we do to them? What are they exposed to?	What do we compare the intervention with?	What happens? What is the outcome?



Two results:
Estimated effect
Quality of evidence

Research methods in epidemiology and clinical medicine

Knowledge research

Descriptive methods
description of
reality

Analytical methods
testing one or more
hypotheses



Descriptive methods – no hypothesis

Case reports

Descriptive
epidemiology

Qualitative studies



Noe å lære av

En tidligere slankeoperert kvinne med magesmerter

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Oppgitte interessekonflikter: Ingen

Se kommentar side 32

Se også kunnskapsprøve
på www.tidsskriftet.no/quiz

En 51 år gammel kvinne ble innlagt i medisinsk avdeling tilleggende øyeblikkelig hjelp pga. synkope. Det kom frem at hun de siste tre ukene før for innleggelsen hadde hatt smerter i epigastriet, sporadisk ledsaget av sure oppstøt og retrosternal svie. Smerterne var måltidrelaterte og kom «straks» etter at hun hadde svelget første matbit. Hun hadde ikke hatt dysfagi, vedstap, oppkast eller endrede avføringsvaner.

Differensialdiagnosene for synkope (kardialt, cerebraalt, vasovagalt, smerte) ble diskutert. Mulige årsaker til pasientens gastrointestinale plager inkluderte ulcusykdom, oesofagusstenose, hiatusherni og pylorusstenose.

Pasienten ble nøye utredet for synkope uten at man påviste noen sikker årsak til denne. Utredningen omfattet kardiologisk og neurologisk undersøkelse inkludert telemetri,

R-test, ekkoundersøkelse av hjertet, EEG, cerebral CT og ortostatisk blodtrykksmåling. Pasienten hadde ikke flere synkoper under oppholdet og var i god allmenntilstand. Imidlertid klaget hun over persisterende måltidrelaterte smerter i epigastriet, sure oppstøt og halsbrann.

Vi visste at pasienten, pga. adipositas, var blitt operert med åpen gastrisk innsværing (banding) 23 år forut for den aktuelle innleggelsen. Derfor ble det også tenkt på muligheten for senkomplikasjoner etter dette som årsak til plagene.

Gastroskopi utført seks dager etter innleggelsen viste at båndet som ble brukt ved operasjonen 23 år tidligere, satt ca. 5 cm distalt for operasjonsstedet. Videre så vi at båndet var

CT-undersøkelse av området ga ingen detalleggsinformasjon. Det var ingen tegn til inflammasjon eller andre patologiske forhold i eller rundt ventrikkel eller i andre abdominalorganer.

Vi bestemte oss for å prøve å fjerne båndet endoskopisk. Vi hadde ingen saks som var lang nok til å komme gjennom arbeidskanalen på skopet, eller parallelt med skopet. Vi bestilte en kirurgisk saks (Reusable surgical scissors F3–31–1, Olympus.) som går gjennom arbeidskanalen på gastroskopet. Minimumsdiameter på arbeidskanalen for å benytte dette instrumentet, er 2,8 mm.

Pasienten ble utskrevet fra sykehuset i god allmenntilstand samme dag som den første gastroskopia ble utført. To dager senere

RESEARCH

Orlistat and the risk of acute liver injury: self controlled case series study in UK Clinical Practice Research Datalink

OPEN ACCESS

Ian J Douglas *lecturer in pharmacoepidemiology*, Julia Langham *lecturer*, Krishnan Bhaskaran *lecturer in statistical epidemiology*, Ruth Brauer *research student*, Liam Smeeth *professor of clinical epidemiology*

Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London WC1E 7HT, UK

Abstract

Objective To measure the association between orlistat and acute liver injury.

Design Self controlled case series study.

Setting Population based primary care setting, United Kingdom.

Participants 94 695 patients receiving orlistat and registered in the UK Clinical Practice Research Datalink and linked with Hospital Episode Statistics data between 1999 and 2011.

Main outcome measure Relative incidence of acute liver injury comparing periods when patients were receiving orlistat with periods of non-usage.

Results Among 94 695 patients who received orlistat, 988 cases of acute liver injury were identified, with 335 confirmed as definite cases and 653 as probable cases. For all cases an increased incidence of liver injury was detected during the 90 day period before orlistat was first started, with an incidence rate ratio of 1.50 (95% confidence interval 1.10 to 2.06). The incidence remained raised during the first 30 days of treatment (2.21, 1.43 to 3.42), before returning to baseline levels with prolonged treatment. When the risk during the first 90 days of treatment was compared with the 90 days preceding first treatment, the incidence of liver injury was not increased (1.02, 0.67 to 1.56). An analysis restricted to definite cases showed no evidence of an increased risk of liver injury during treatment.

Conclusion The incidence of acute liver injury was higher in the periods both immediately before and immediately after the start of orlistat treatment. This suggests that the observed increased risks of liver injury linked to the start of treatment may reflect changes in health status associated with the decision to begin treatment rather than any causal effect of the drug.

a reduction in dietary fat lipolysis and absorption.⁴ Although mild but unpleasant gastrointestinal side effects are commonly reported with orlistat use there is also concern that it may be associated with an increased risk of serious hepatic events. The US Food and Drug Administration first issued a warning about a possible link between orlistat and serious liver injury in 2009² based on an analysis of 32 case reports received between 1999 and 2008. The European Medicines Agency has also reviewed the strength of evidence relating to this possible risk.³ The analysis of individual case reports is often unable to give reliable conclusions about causality and a range of population based studies are needed to help inform decisions about the likely risks and benefits of orlistat. A meta-analysis of clinical trial data involving around 10 000 patients found no evidence that orlistat was associated with increases in selected variables of liver function,⁴ and a likely mechanism of action has not been identified. Assessments by both agencies concluded that there was no strong evidence to determine a causal association. However, results from clinical trials do not always reflect the effects of drugs when used in the general population, and to date no studies have been published based on orlistat use in the real world. Orlistat remains the only drug treatment option for obesity, is widely used, and in many countries is available without prescription. Further clarity on safety is therefore needed.

People using orlistat are likely to have a different underlying risk of acute liver events from non-users owing to obesity and its comorbidities, and many study designs would be unable to fully account for these important differences. We conducted a self controlled case series study in which each participant acts

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<http://dx.doi.org/10.1155/2013/124664>



Case Report

Acute Oxalate Nephropathy Associated with Orlistat: A Case Report with a Review of the Literature

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Orlistat is a gastrointestinal lipase inhibitor used for weight reduction in obese individuals. Enteric hyperoxaluria caused by orlistat leads to oxalate absorption. Acute oxalate nephropathy is a rare complication of treatment with orlistat. Herein we report a patient presenting with acute renal failure which improved minimal with intravenous hydration. She was found to have oxalate crystals on renal biopsy. Patient admitted orlistat use over the counter for weight reduction on further questioning. The purpose of this case review is to increase awareness among patients since they are more focused on losing weight. This case also calls for the provider attention to educate patients regarding side effects of orlistat because of easy availability of orlistat over the counter.



Original Investigation

Prevalence of Childhood and Adult Obesity in the United States, 2011-2012

Cynthia L. Ogden, PhD; Margaret D. Carroll, MSPH; Brian K. Kit, MD, MPH; Katherine M. Flegal, PhD

IMPORTANCE More than one-third of adults and 17% of youth in the United States are obese, although the prevalence remained stable between 2003-2004 and 2009-2010.

OBJECTIVE To provide the most recent national estimates of childhood obesity, analyze trends in childhood obesity between 2003 and 2012, and provide detailed obesity trend analyses among adults.

DESIGN, SETTING, AND PARTICIPANTS Weight and height or recumbent length were measured in 9120 participants in the 2011-2012 nationally representative National Health and Nutrition Examination Survey.

MAIN OUTCOMES AND MEASURES In infants and toddlers from birth to 2 years, high weight for recumbent length was defined as weight for length at or above the 95th percentile of the sex-specific Centers for Disease Control and Prevention (CDC) growth charts. In children and adolescents aged 2 to 19 years, obesity was defined as a body mass index (BMI) at or above the 95th percentile of the sex-specific CDC BMI-for-age growth charts. In adults, obesity was defined as a BMI greater than or equal to 30. Analyses of trends in high weight for recumbent length or obesity prevalence were conducted overall and separately by age across 5 periods (2003-2004, 2005-2006, 2007-2008, 2009-2010, and 2011-2012).

RESULTS In 2011-2012, 8.1% (95% CI, 5.8%-11.1%) of infants and toddlers had high weight for recumbent length, and 16.9% (95% CI, 14.9%-19.2%) of 2- to 19-year-olds and 34.9% (95% CI, 32.0%-37.9%) of adults (age-adjusted) aged 20 years or older were obese. Overall, there was no significant change from 2003-2004 through 2011-2012 in high weight for recumbent length among infants and toddlers, obesity in 2- to 19-year-olds, or obesity in adults. Tests for an interaction between survey period and age found an interaction in children ($P = .03$) and women ($P = .02$). There was a significant decrease in obesity among 2- to 5-year-old children (from 13.9% to 8.4%; $P = .03$) and a significant increase in obesity among women aged 60 years and older (from 31.5% to 38.1%; $P = .006$).

CONCLUSIONS AND RELEVANCE Overall, there have been no significant changes in obesity prevalence in youth or adults between 2003-2004 and 2011-2012. Obesity prevalence remains high and thus it is important to continue surveillance.

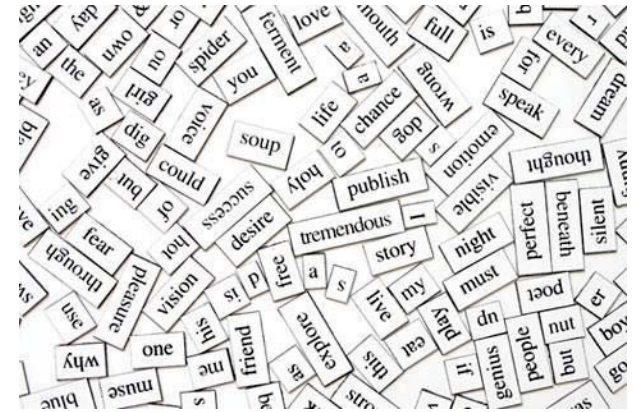
JAMA. 2014;311(21):2062-2074. doi:10.1001/jama.2014.722

Supplemental content at jama.com

Author Affiliations: National Center for Health Statistics, Centers for Disease Control and Prevention, Hyattsville, Maryland (Ogden, Carroll, Kit, Flegal); United States Public Health Service, Rockville, Maryland (Kit).

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Qualitative research methods



It is used in the exploration of meanings of social phenomena as experienced by individuals themselves, in their natural context

Investigates (why and how not just what, where, when)

Wikipedia



PAPER

Weight maintenance and relapse in obesity: a qualitative study

S Byrne^{1*}, Z Cooper¹ and C Fairburn¹

¹University of Oxford, Department of Psychiatry, Warneford Hospital, Oxford OX3 7JX, UK

OBJECTIVE: To investigate, among women with obesity who have lost weight, the psychological factors associated with successfully maintaining the new lower weight, as opposed to weight regain.

DESIGN: Qualitative research methods (in-depth individual interviews and group interviews) were used to investigate characteristics of successful weight maintainers, as compared with weight regainers and healthy-weight women.

SUBJECTS: In all, 76 females were recruited from the community, comprising 28 formerly obese women who had lost weight and maintained their new lower weight for at least 1 y; 28 obese women who had lost weight but regained the weight; and 20 women with a stable weight in the healthy range.

RESULTS: Certain psychological factors were identified which characterised the regainers but not the maintainers. These were: failure to achieve weight goals and dissatisfaction with the weight achieved; the tendency to evaluate self-worth in terms of weight and shape; a lack of vigilance with regard to weight control; a dichotomous (black-and-white) thinking style; and a tendency to use eating to regulate mood.

Conclusion: The results suggest that psychological factors may provide some explanation as to why many people regain weight following successful weight loss. The factors identified in this study need to be examined further using quantitative designs.

International Journal of Obesity (2003) 27, 955–962. doi:10.1038/sj.ijo.802305

Keywords: weight maintenance; weight regain; psychological factors

Qualitative research

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doi:10.1093/heapro/dah053
Advance access publication 24 January 2005

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Healthy eating, activity and obesity prevention: a qualitative study of parent and child perceptions in Australia

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Centre for Community Child Health, Murdoch Childrens Research Institute and University of Melbourne, Royal Children's Hospital, Parkville, Victoria, Australia

SUMMARY

Preventative health strategies incorporating the views of target participants have improved the likelihood of success. This qualitative study aimed to elicit child and parent views regarding social and environmental barriers to healthy eating, physical activity and child obesity prevention programmes, acceptable foci, and appropriate modes of delivery. To obtain views across a range of social circumstances three demographically diverse primary schools in Victoria, Australia were selected. Children in Grades 2 (aged 7–8 years) and 5 (aged 10–11 years) participated in focus groups of three to six children. Groups were semi-structured using photo-based activities to initiate discussion. Focus groups with established parent groups were also conducted. Comments were recorded, collated, and themes extracted using grounded theory. 119 children and 17 parents participated. Nine themes emerged: information and awareness, contradiction between

knowledge and behaviour, lifestyle balance, local environment, barriers to a healthy lifestyle, contradictory messages, myths, roles of the school and family, and timing and content of prevention strategies for childhood obesity. In conclusion, awareness of food 'healthiness' was high however perceptions of the 'healthiness' of some sedentary activities that are otherwise of benefit (e.g. reading) were uncertain. The contradictions in messages children receive were reported to be a barrier to a healthy lifestyle. Parent recommendations regarding the timing and content of childhood obesity prevention strategies were consistent with quantitative research. Contradictions in the explicit and implicit messages children receive around diet and physical activity need to be prevented. Consistent promotion of healthy food and activity choices across settings is core to population prevention programmes for childhood obesity.

Key words: diet; obesity; physical activity; qualitative

“Qualitative researchers aim to gather an in-depth understanding of human behavior and the reasons that govern such behavior. The qualitative method investigates the why and how of decision making, not just what, where, when. Hence, smaller but focused samples are more often used than large samples.”

Wikipedia

Research methods in epidemiology and clinical medicine

Knowledge research

Descriptive methods
description of reality

**Analytical methods
testing one or more
hypotheses**



Hypothesi

S

Proposed explanation for an observable phenomenon

Assumption that can be confirmed (verified) or disproved (falsified)

Hypotheses must

- Be specific

- Not include value-laden words

- Be “testable”

Analytical methods

Observational
cross-sectional
studies
case-control studies
cohort studies

Experimental
controlled clinical
trials
interventional
studies



Cross-sectional studies

Hypotheses are tested by examining a cross section of the population

Everything happens at the same time

Must find an appropriate group
(representativeness)

Can not explain causal links



Cross-sectional study

Does breast feeding protect against obesity?

Study among children of a randomly selected sample (n=2584) of the members of the 1958 British birth cohort. 2631 children included: data on breast feeding, BMI and confounding factors (birth weight, mother's smoking, social class).

We found no evidence that breast feeding influenced body mass index or obesity and no dose dependent trend in either age group»



Case-control studies

Retrospective studies (looking back in time)

Compares "cases" (with disease) with controls (without disease) to find differences

Especially well suited for rare disorders

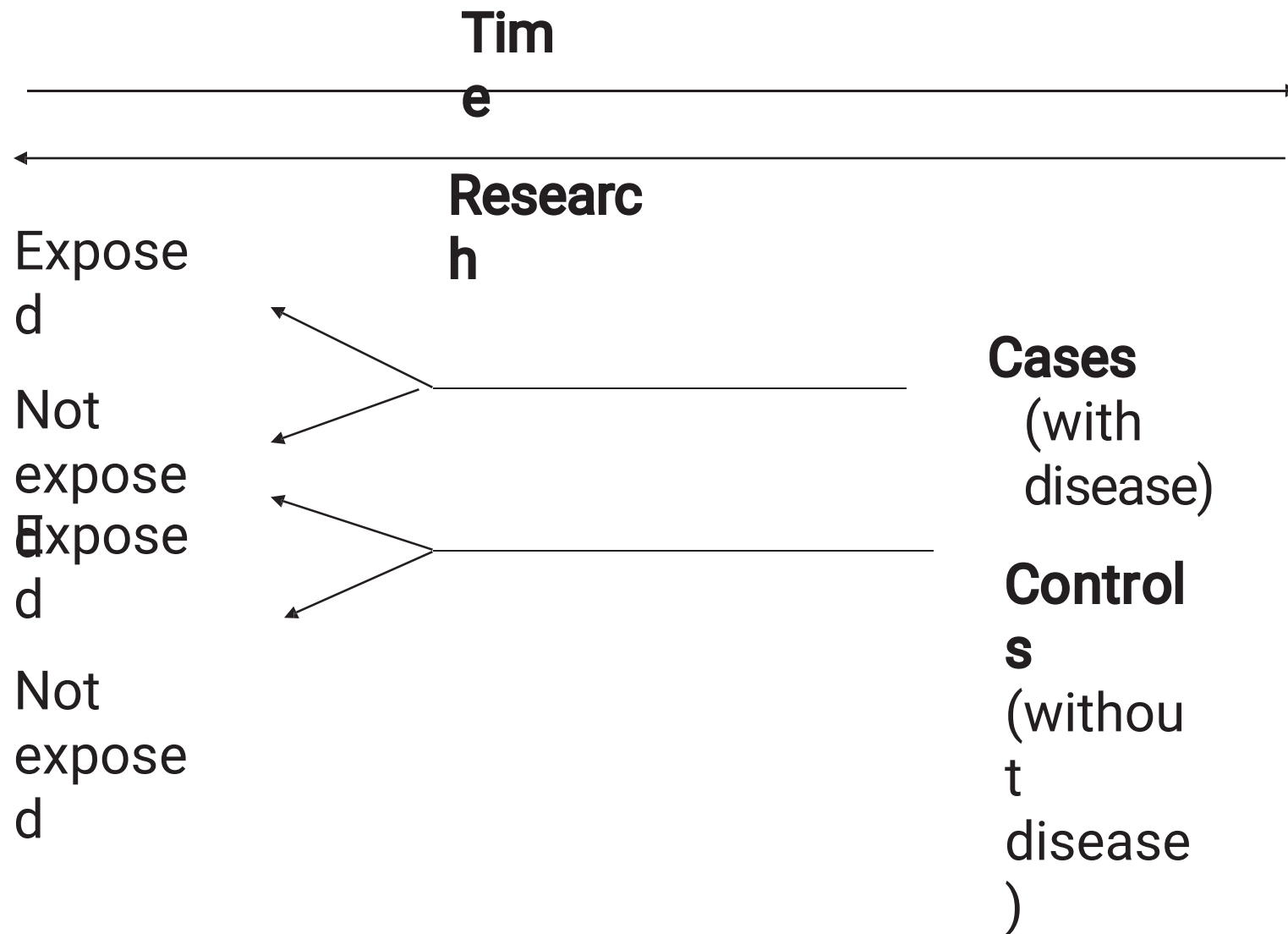
Method problems

- Bias

- Selection of controls



Case-control study – retrospective study



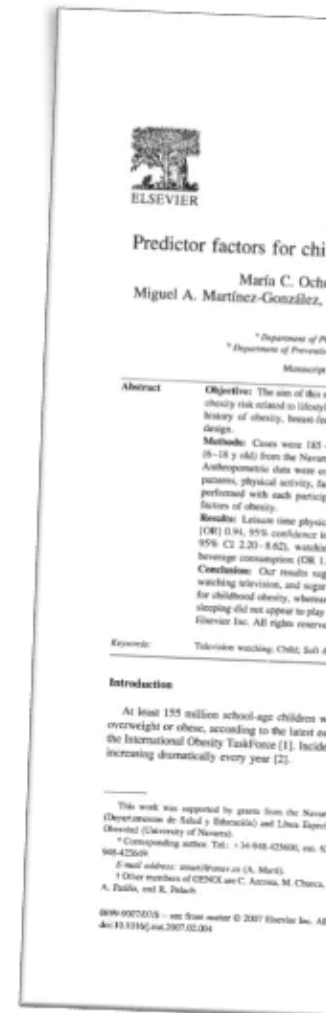
Cases were 185 obese children
(6- 18 years) - controls matched
by sex and age

Protective factor against obesity:
Leisure time activity

Associated with a higher
risk:

Family history of obesity
Watching television
Sugar-sweetened
beverage consumption

Of no importance:
Breast feeding
Birth weight
Time spent sleeping



Cohort study

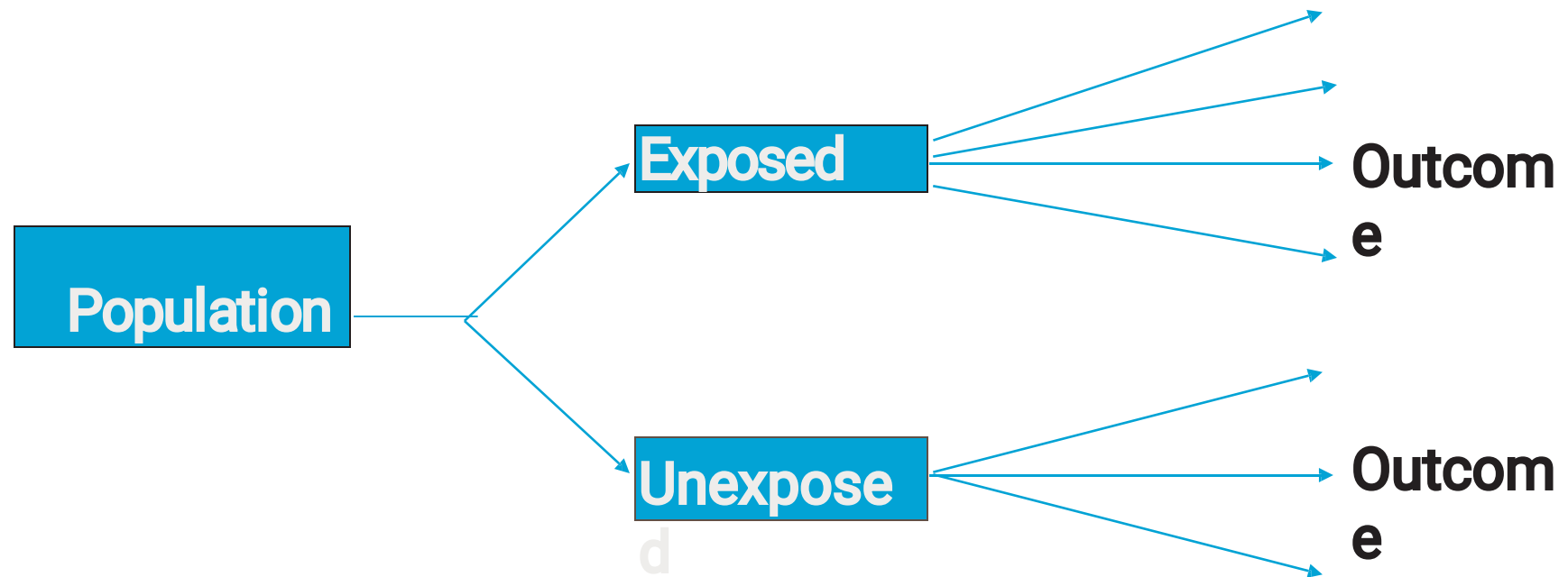
Prospective (looking forward in time)

Compare a group with a characteristic/exposure
with a group without this characteristic/exposure

Expensive and time consuming design



Cohort study – prospective study



Experimental studies

Interaction

The goal is complete control over all aspects

Aiming at isolating the phenomenon investigated by correcting for other factors



Controlled clinical trials

Follow patients over time

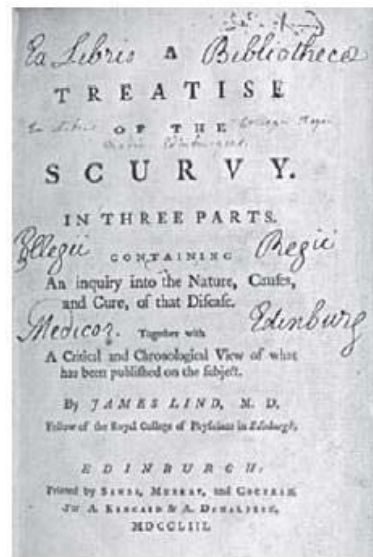
Comparing the intervention group with control group

Randomizing techniques

Blinding?



The First Trial?



James Lind (1716-1794), Scottish naval surgeon, pictured with the books he wrote, and the title page of the most famous of these, in which he recorded a controlled trial done in 1747 showing that oranges and lemons were a more effective treatment for scurvy than five other treatments then in use (see www.jameslindlibrary.org).

Scurvy
12 Patients

Cider

Elixir of vitriol

Vinegar

Sea water

Oranges &
Lemons

Barley water

James Lind

Year 1747

What is good research?

Research is producing **new understanding of reality** by “cultivating” facts.

Research provides simple statements with **generalizability**

Albert Einstein (1879 1955)

Good research

High quality research....

Based on scientific **methods**

Can provide **new knowledge** about
health and illness

Safe for participants (ethically and
medically acceptable)

Summing up

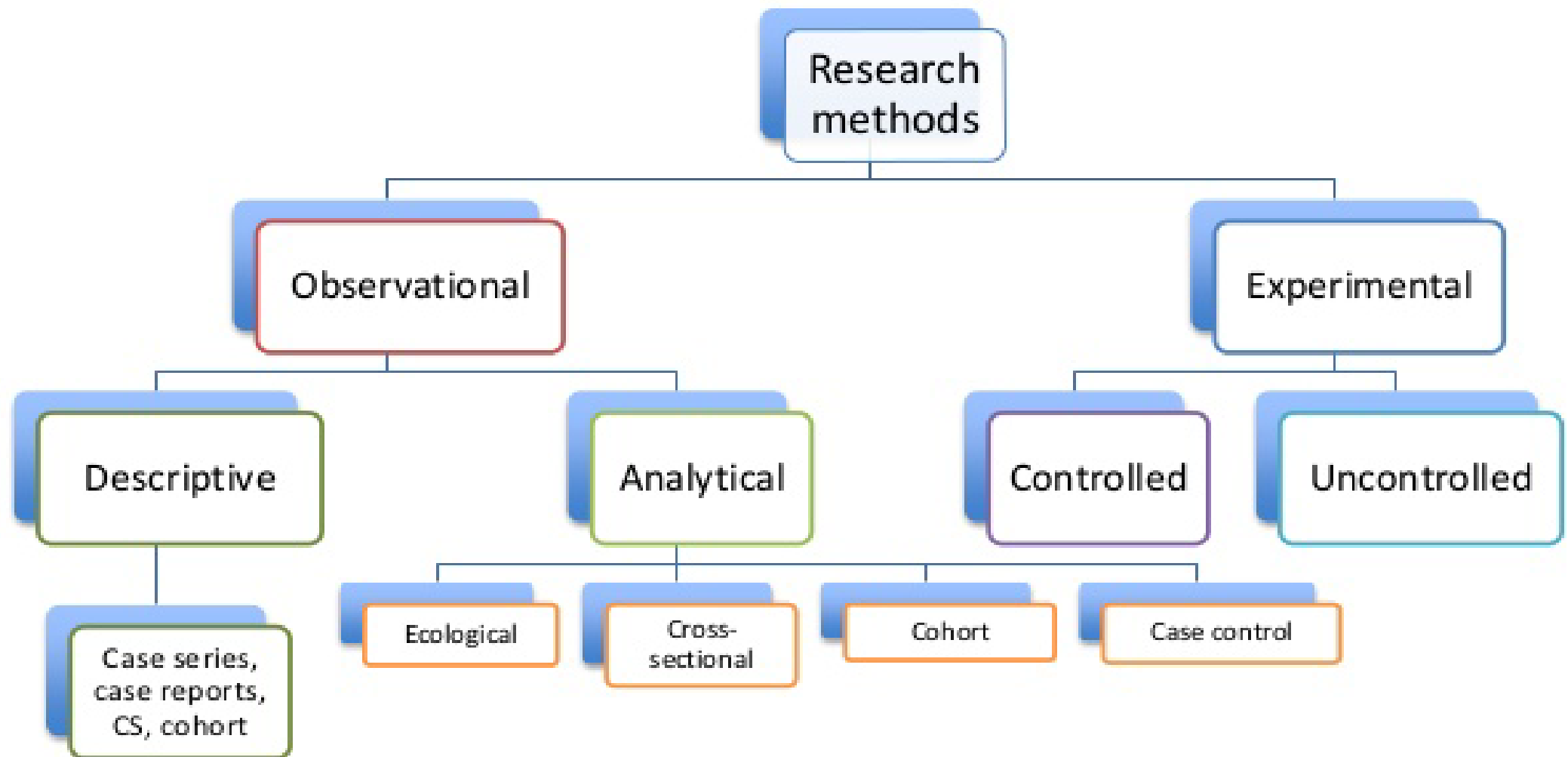
Health research is different from health care

Research methods should be chosen
according to the question to be answered

Describe your method so others can
understand what you did

To play by the rules, you have to know the
rules

Classification of research methods



Thank You!