






INTRODUCTION TO DRUG UTILISATION RESEARCH (DUR) WITH EMPHASIS ON METHODOLOGIES

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Overview of presentation



- Introduction
- Rational use of medicines
- Definition of drug utilisation research (DUR)
- DUR process
- Purposes of DUR
- Types of DUR studies
- Study methodologies
- Data sources
- Classification systems
- [Practical examples]



Outcomes

On completion of this workshop, participants will be:

- Familiar with the various drug utilisation research methodologies (quantitative and qualitative)
- Able to conduct a basic research project and be familiar with the different steps involved
- Analyse and interpret treatment and medicine usage patterns and the factors involved from different perspectives

Rational use of medicines

- Right patient
- Right indication/diagnosis
- Right medicine
- Right dose/administration
- Right information
- Right moment to stop or change



Inappropriate drug use

- Adverse effects
- Sub-optimal outcomes
- Waste of resources
 - Money
 - Health professionals' time
 - Patients' time



Reasons why are drugs not used rationally

- Lack of training and knowledge
- Marketing practices
- Financial incentives for irrational use
- Availability problems (e.g. out of stock)
- Patient expectations
- Prescribing as a means to finish the consultation
- Health systems and services effects
- And many more ...

DUR

DUR

- = Drug utilisation review
- = Drug utilisation research

Medicine Utilisation Research in Africa

MURIA

Website: <http://muria.nmmu.ac.za/>



What is research?

If you know ...

- What you are doing
- How long it will take
- What it will cost
- What you will discover

IT IS **NOT** RESEARCH...!!!!



Drug utilisation RESEARCH (Review)

Systematic inquiry → Outcomes:

- Project write-ups in the form of research reports (articles)
- Research presentations/posters
- Improvement of health care systems – for patients



MOTIVATION ...

Viewpoint

Disease burden in sub-Saharan Africa: what should we conclude in the absence of data?



Richard S Cooper, Babatunde Osotimehin, Jay S Kaufman, Terrence Forrester

Published in: Lancet, 1998; 352: 208-201.



Drug utilisation

Defined as ...

"the prescribing, dispensing, administering, and ingesting of drugs" (Serradell, *et al.*, 1987: 994)

World Health Organisation (WHO) definition (1977):

"The marketing, distribution, prescription, and use of drugs in society, with special emphasis on the resulting medical, social, and economic consequences" (Serradell, *et al.*, 1987: 994)



WHO Guideline

<http://apps.who.int/medicinedocs/pdf/s4876e/s4876e.pdf>

Introduction to Drug Utilization Research

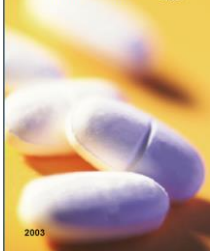


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- Acknowledgements



Drug Utilization Research: Methods and Applications - 2016

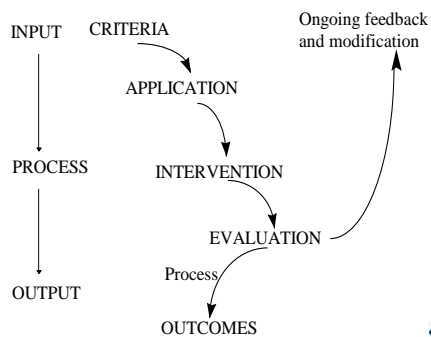


Where do you start?

- Method?
- For what reason?
- How will the outcome be used?



Systems view of drug utilisation



Drug Utilisation Review (DUR) process

- Design the basic structure
- Seek approval
- Construct indicators and criteria
- Apply indicators and criteria to database
- Evaluate and analyse yield (data)
- Establish prescribing patterns
- Establish intervention strategies
- Measure outcomes
- Reapply criteria to database
- Revise indicators and criteria as needed



Purposes of DUR

- Improvement of the **quality** of care
- Containment of the **cost** of medical care
- Identification and control of **fraud and abuse**



Types of Drug Utilisation Review

- Retrospective studies
- Concurrent reviews
- Prospective reviews



From DUR to intervention

- **Drug utilisation studies**
Tend to be descriptive, aggregate data ("What?")
- **Indicator studies**
More focused on rational drug use ("What? → How much?")
- **Qualitative studies** ("Why?")
- **Intervention studies**
How much? Why? → *Intervention* → "How much now?"
Conclusion → Does it work? Is the intervention effective?
- **Management studies**
Is the intervention reproducible?
Is it cost-effective?



STUDY METHODOLOGIES



Methods used in drug utilisation studies

- Studies on prescription habits
- Studies on patient compliance
- Studies on drug effects
- Studies on patients' knowledge about drugs
- Ad hoc studies
- Methods used in qualitative studies
- Descriptive studies, determinants of drug utilisation and impact of drug use
- Consumption studies
 - Cost studies
 - Studies based on numbers of units sold
 - Studies on prescription volume
 - Defined Daily Dose (DDD) and Prescribed Daily Dose (PDD)



Studies on prescription habits

For reprint orders, please contact: reprints@futuremedicine.com

Statin prescribing among hypertensive patients in southwest Nigeria: findings and implications for the future

Journal of **Comparative Effectiveness Research**

Background: Statins reduce cardiovascular risk, especially in patients with hypertension due to their concomitant blood pressure reducing effects. Prescribing generic statins minimizes cost and improves access. **Aims:** Ascertain current prescribing of statins in Nigeria and potential savings from the increased use of generic statins. **Methods:** Prospective study involving hypertensive patients attending University College Hospital (Ibadan, Nigeria). **Results:** In total, 228 hypertensive patients received statins. Atorvastatin was the most prescribed statin, followed by simvastatin, rosuvastatin and finally fluvastatin. Prescribed doses were less than one defined daily dose in the majority, with high use of originators. Average monthly potential savings from

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Studies on patient compliance

Medicine possession ratio as proxy for adherence to antiepileptic drugs: prevalence, associations, and cost implications

This article was published in the following Cross Press journal:
Patients, Preference and Adherence
12 April 2015
<http://dx.doi.org/10.1016/j.ppa.2015.04.001>

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Objective: To determine the adherence status to antiepileptic drugs (AEDs) among epilepsy patients; to observe the association between adherence status and age, sex, active ingredient prescribed, treatment period, and number of comorbidities; and to determine the effect of nonadherence on direct medicine treatment cost of AEDs.

Methods: A retrospective study analyzing medicine claim data obtained from a South African pharmaceutical benefit management company was performed. Patients of all ages ($N=10,168$), who received more than one prescription for an AED, were observed from 2008 to 2013. The modified medicine possession ratio (MPR) was used as proxy to determine the adherence status to AED treatment. The MPR was considered acceptable (adherent) if the calculated value was ≥ 0.8 , but < 1.0 , whereas an MPR of < 0.8 (inadequately low) or > 1.0 (inadequately high) was considered nonadherent. Direct medicine treatment cost was calculated by summing the medical scheme contribution and patient co-payment associated with each AED prescription.

Results: Only 55% of AEDs prescribed to 10,168 patients during the study period had an acceptable MPR. MPR categories depended on the treatment period ($P<0.0001$); Cramer's $V=0.200$ but were independent of sex ($P<0.142$), Cramer's $V=0.000$. Age group ($P<0.0001$), Cramer's $V=0.067$, active ingredient ($P<0.0001$), Cramer's $V=0.071$, and number of comorbidities ($P<0.0001$), Cramer's $V=0.150$ were statistically but not practically significantly associated with MPR categories. AEDs with an inadequately high MPR contributed to 3.54% (US\$736,376.72) of the total direct cost of all AEDs included in the study, whereas those with an inadequately low MPR amounted to US\$2,272,944.85 (3.30%).

Conclusion: Nonadherence to antiepileptic treatment is a major problem, encompassing ~20% of cost expenditure. Adherence to antiepileptic treatment is a major problem, encompassing ~20% of cost expenditure. Adherence to antiepileptic treatment is a major problem, encompassing ~20% of cost expenditure.



Studies on drug effects

J. Endocrinol. 1994 Dec; 125(3 Pt 1): 987-91.

Bioequivalence of a generic slow-release theophylline tablet in children.

Pantthanasitana S¹, Ahrens RG, McCubbin M, Boersky E, Blalock K, Hendelberg L.

¹ Author information

Abstract

OBJECTIVE: To determine whether a generic slow-release theophylline tablet (manufactured by Sidmak Laboratories, Inc.) is therapeutically equivalent to a proprietary theophylline tablet, Theo-Dur, in children.

DESIGN: Prospective, randomized, double-blind, crossover trial.

SETTING: Multicenter clinics.

PATIENTS: 38 children, 6 to 16 years of age, with asthma.

INTERVENTIONS: Individualized doses of Theo-Dur or generic tablet every 12 hours for 5 days.

MEASUREMENTS AND MAIN RESULTS: During the last 24 hours of each regimen, theophylline serum concentrations were measured serially and a standardized exercise stress test was performed at 24 hours (trough serum concentration). Neither formulation effectively blocked the response to exercise; the maximum decrease in forced expiratory volume in the first second was 26.1% +/- 18.9% with Theo-Dur and 24.8% +/- 19.7% with the generic product ($p = 0.68$; $\beta = 0.08$). The mean +/- SD peak serum concentrations were 18.0 +/- 3.0 micrograms/ml with Theo-Dur and 18.7 +/- 3.7 micrograms/ml with the generic tablet, the trough serum concentration was < 10 micrograms/ml in 15 subjects after administration of Theo-Dur and in 20 subjects after administration of the generic product. There were no significant differences in relative extent of absorption or the time to reach peak serum concentration.

CONCLUSIONS: This generic formulation and Theo-Dur are bioequivalent in children. However, these results cannot be extrapolated to slow-release theophylline formulations that have not been approved by the U.S. Food and Drug Administration as equivalent to Theo-Dur.

Studies on patients' knowledge about drugs

PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 2004; 13: 871–876
Published online 28 September 2004 in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/pds.1020

ORIGINAL REPORT

Patient knowledge about drugs prescribed at primary healthcare facilities

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SUMMARY

Objective Providing adequate information to the patients about their drugs is an essential principle of rational pharmacotherapy. This study investigates the knowledge of general practice patients about their drugs, since the level of knowledge of the patient about the medication is highly associated with the outcome of the therapy.

Methods A total of 1618 patients who applied to primary healthcare centers in Istanbul and accepted to participate in the study were asked about the name(s) and effect(s) of the drug(s) on their prescriptions. Factors that might influence the background knowledge and perception of patients such as sociodemographic characteristics, drug-use habits and practitioners' attitudes were also questioned. Information provided by the patients was compared with the prescriptions.

Results Only 10.9% of the respondents could recall the names of their drug(s) correctly. Level of education, and gender, had a positive impact on recalling drug names. Patients, who received a refill prescription, with a chronic disease, and who had self-medication before applying to the health center reported more accurate information. Less than half of the practitioners had informed their patients about the drug effects; and 7% of the patients have been requested to repeat the instructions and warnings about further medication(s). The patients to name their drugs correctly also knew the drug effects twice as much as the patients who could not recall their drugs correctly. The drug-use habits were not related to the level of knowledge.

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Ad hoc studies

Int J Clin Pharmacol Ther. 2003 Apr;41(4):165-70.

Impact of analgesic drug-use guidelines for the management of postoperative pain: a drug utilization study.

Villars A¹, Ullmann J, Amann JM, Martorell M, Girson L, Laporte JB.

¹ Author information

Abstract

OBJECTIVE: Postoperative pain is inadequately treated in many surgical settings. The present study evaluates the impact of analgesic drug-use guidelines in the management of postoperative pain.

PATIENTS AND METHODS: A prospective drug utilization study was carried out in 3 stages in a traumatology, orthopedic and rehabilitation tertiary hospital. The first stage, aimed at describing the patterns of use of analgesic strategies in the management of postoperative pain, identified habits, practices and misconceptions regarding this therapeutic area. After this, an ad hoc representative institutional working group agreed on analgesic drug-use guidelines for the management of postoperative pain. These were then published, presented and discussed with surgeons and nurses. After the guidelines had been implemented, their impact was evaluated in terms of the analgesics used, their dosage and their administration schedule.

RESULTS: 101 patients were studied before the implementation of the guidelines and 100 patients after. Patients receiving opiate analgesics during the immediate postoperative period increased from 70.94% ($p < 0.05$). First-choice analgesics used according to the guidelines increased from 40.89% of choices after the implementation of the guidelines ($p < 0.05$). Administration of analgesics at regular predetermined intervals increased from 45.58% of medical orders, but this increase was not statistically significant ($p = 0.07$). Prescription of analgesics at adequate doses increased from 67.87% ($p < 0.05$).

CONCLUSION: Education on the treatment of postoperative pain is made up of several messages including the drug of choice and dose regimen. Prescribers seemed more receptive to a change in drug rather than issues related to the correct dose regimen. More research is needed to assess how educational activities can improve the management of postoperative pain.

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Methods used in qualitative studies

Journal of Multidisciplinary Healthcare

Dovepress

OPEN ACCESS, PEER-REVIEWED AND CITED PUBLISHED

ORIGINAL RESEARCH

An exploratory qualitative study on perceptions about mosquito bed nets in the Niger Delta: what are the barriers to sustained use?

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Volume 2017
Number 1
DOI: 10.1515/jmh-2017-0001

Background: The effectiveness of malaria control programs is determined by an array of complex factors, including the acceptability and sustained use of preventive measures such as the bed net. A small-scale exploratory study was conducted in several locations in the Niger Delta region, Nigeria, to discover barriers against the use of bed nets, in the context of a current drive to scale up net use in Nigeria.

Methods: A qualitative approach with a convenience sample was used. One to one interviews with mostly male adult volunteers were conducted which explored typical living and sleeping arrangements, and perceptions about and barriers against the use of the mosquito prevention bed net.

Results: Several key issues emerged from the qualitative data. Bed nets were not reported as widely used in this small sample. The reasons reported for lack of use included issues of convenience, especially net set-up and dismantling; potential hazard and safety concerns; issues related to typical family composition and nature of accommodation; humid weather conditions; and perceptions of cost and effectiveness. Most barriers to net use concerned issues about everyday practical living, and sleeping arrangements and perceptions about comfort. Interviewees identified were aware of malaria infection risks, but several also indicated certain beliefs that were barriers to net use.

Conclusions: Successful control of malaria and scale up of insecticide-treated net coverage relies on community perceptions and practices. This small study has identified a number of important everyday life issues, which remain barriers to sustained net use, and have clarified further

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Descriptive studies, determinants of drug utilisation and impact of drug use

Research article

Open Access

A descriptive review of the methodologies used in household surveys on medicine utilization

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Abstract

Background: Studies carried out in the community enable researchers to understand access to medicines, affordability, and barriers to use from the consumer's point of view, and may stimulate the development of adequate medicines policies. The aim of the present article was to describe methodological and statistical aspects of quantitative studies on medicine utilization carried out at the household level.

Methods: Systematic review of original papers with data collected in studies in which the household was a sampling unit, published between 1995 and 2008. The electronic review was



Consumption studies

Antimicrobial prescribing in South Africa using a large pharmacy database: A drug utilisation study

Rae Teiser

Published: 3 February 2009
BMC Health Services Research 2009, 9:22
doi:10.1186/1471-2431-9-22
Received: 10 November 2008
Accepted: 10 November 2008

Available from: <http://www.biomedcentral.com/1471-2431/9/22>

Abstract

The primary aim was to determine the general prescribing trends of antimicrobial drugs to patients whose prescriptions were dispensed by community pharmacies. A retrospective, cross-sectional drug utilization study was conducted on 2005 data of a national community pharmacy group in South Africa. A total of 600,530 patients received 1,276,562 antimicrobial products during 2005. The average age of patients was 34.23 (SD = 19.82) years. Most patients were female (58.22%). Patients between 40 and 49 years received the highest average of 2.22 antimicrobial prescriptions during the year. Beta-lactams were the most often prescribed (24.53% of antimicrobial prescriptions), followed by antifungal agents (20.92%) and quinolones (11.12%). Differences were observed between females and males with respect to the prescribing frequency of different antimicrobial classes ($p < 0.001$), especially between antifungal agents and beta-lactam antibiotics. Within the beta-lactam class, penicillins accounted for 76.47% of products and cephalosporins for 23.49%. The most frequently prescribed trade name product was a generic combination of amoxicillin and clavulanic acid. Antifungal agents were the most expensive (R101.42), followed by aminoglycosides (R108.42). Prescribing peaked during the winter months. This study provides a general overview of antimicrobial prescribing that can be used for comparative studies with other population groups. African countries will be more specific investigations.

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Available from: <http://www.biomedcentral.com/1471-2431/9/22>

Introduction

Antimicrobial prescribing is a primary care issue globally world-wide during the last decade. There are concerns about some common infections which are becoming increasingly difficult to treat. Several studies have demonstrated that patterns of antibiotic use greatly affect

availability and effectiveness of antimicrobials required to treat infections. Problems of increased mortality, costs of extended hospitalization and mortality are extremely serious in terms of their impact on the quality of life of patients as well as the economic impact. The problem of susceptibility to and spread of infections caused by antibiotic-resistant



Quantitative vs Qualitative DUR

Quantitative DUR

- Quantification of data (measurements, counts, summaries ...)
- Hypotheses testing
- Causal relationship between measurable variables
- Results with some degree of confidence

Qualitative DUR

- Looking for the quality of events
- Exploration of social phenomena
- Gaining insight into the context
- Giving emphasis to the meanings, experiences and views of participants



Example: Patient compliance

Quantitative DUR

Quantification, relations, significance

- What is the frequency of non-compliance?
- Relationship between age and non-compliance?
- Relationship between gender and non-compliance?

Qualitative DUR

Exploration, meaning, understanding

- Why are younger patients not compliant?
- What are the thoughts among pharmacists about non-compliance in patients on anti-hypertensives?



Activity

■ South Africa

- Medicine A is sold in pack sizes of 28 tablets for the 20 mg dosage strength

■ Botswana

- Medicine A is sold in pack sizes of 28 tablets for the 20 mg dosage strength

■ Namibia

- Medicine A is sold in pack sizes of 28 tablets for the 20 mg dosage strength
- Medicine A is also sold in pack sizes of 60 tablets for the 10 mg dosage strength

How do we conduct a cross-national comparative study?



Descriptive and analytical methods

■ Measurement units:

- Number of prescriptions
- Number of products
- Number of tablets/capsules
- Cost/expenditure
- DDDs
- PDDs

■ Analyse individual usage patterns:

- Persistence, switching ...



Descriptive and analytical methods

- Biostatistical methods:
 - Descriptive statistics
 - Sampling
 - Significance
 - Correlation
 - Regression analysis ...



CLASSIFICATION SYSTEMS



To standardise studies, need ...

- A drug classification system
 - ATC
 - MIMS
 - BNF
 - Others
- A disease classification system
 - ICD-10
 - Others



Drug Classification System

Anatomical Therapeutic Chemical (ATC) classification system

Download from:

https://www.whocc.no/filearchive/publications/2017_guidelines_web.pdf



Disease Classification System



Website: <http://apps.who.int/classifications/icd10/browse/2015/en>

ICD-10 Version:2015

ICD-10 Code



- ICD-10 Version:2015
- I Certain infectious and parasitic diseases
- II Neoplasms
- III Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
- IV Endocrine, nutritional and metabolic diseases
- V Mental and behavioural disorders
- VI Diseases of the nervous system
- VII Diseases of the eye and adnexa
- VIII Diseases of the ear and mastoid process
- IX Diseases of the circulatory system
- X Diseases of the respiratory system
- XI Diseases of the digestive system
- XII Diseases of the skin and subcutaneous tissue
- XIII Diseases of the musculoskeletal system and connective tissue
- XIV Diseases of the genitourinary system
- XV Pregnancy, childbirth and the puerperium
- XVI Certain conditions originating in the perinatal period
- XVII Congenital malformations, deformations and chromosomal abnormalities
- XVIII Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified
- XIX Injury, poisoning and certain other consequences of external causes
- XX External causes of morbidity and mortality

DATA SOURCES & DATA COLLECTION



Data

Primary (original) data

- Individuals
 - Patient-reported data (also consumer-reported data)
 - Health care worker-reported data
- Documents (Prescriptions, medical records, dispensing records)

Secondary data

- Use existing data

Quantitative or qualitative data, or both?



Data collection

Forms for data extraction & abstraction

Questionnaires

- Structured or unstructured
- Self-designed or existing validated questionnaires
- In person, by telephone, post/online
- Format: open-ended questions, category questions, list options, rating scales (e.g. Likert scale)

Interviews

- Face-to-face
- Telephone
- Self-administered (including web-based)

NB: Data verification



Questionnaire surveys



In-depth interviews (*Qualitative Workshop*)



A cartoon illustration of two people sitting in office chairs, facing each other. The person on the left is a woman with long brown hair, wearing a purple long-sleeved shirt and green pants, gesturing with her hands as if speaking. The person on the right is a man with short blonde hair, wearing a blue long-sleeved shirt and green pants, holding a clipboard and looking towards the woman. They are both wearing purple sneakers.



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Focus groups (*Qualitative Workshop*)



A cartoon illustration of a focus group discussion. Six people are seated around a light blue rectangular table. From left to right: a man in a light blue shirt and brown trousers, a woman in a purple top, a man in a dark blue suit pointing his right index finger upwards, a woman in a red top, a man in a brown jacket, and a woman in a green top. They are all looking towards the man in the suit. The table has papers and pens on it. The background is plain white.



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1996



DATA ANALYSIS – Computerised Rx records

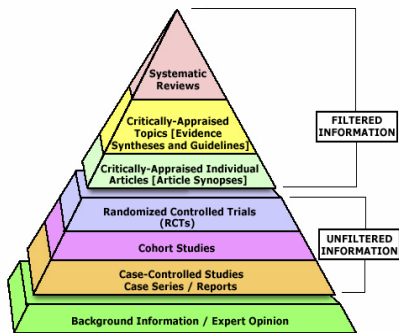
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Empirical sources

- **Databases**
 - Drug industry, wholesalers, medical records, pharmacy dispensing records, claims/reimbursement databases, disease-based registers
- **Data collection from patients or health care providers**
 - Questionnaire surveys, interviews, monitoring devices
- **Prescribing and reimbursement regulations**
- **Principles of clinical pharmacology**
 - Rational use of drugs
 - Guidelines
 - Pharmacovigilance/adverse drug reaction reporting



Study designs



Systematic reviews

- **Seeks to systematically search for, appraise and synthesis research evidence, often adhering to guidelines on the conduct of a review**
- **Examples of websites for systematic reviews:**
 - The Cochrane Library www.cochrane.org
 - The Centre for Evidence-Based Medicine www.cebm.net
 - Bandolier www.medicine.ox.ac.uk/bandolier
 - PubMed Clinical Queries: Find Systematic Reviews www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml

Example of article:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4860284/>



Figure 1. Flowchart of systematic review

Meta-analysis

"Conducting research on research"

Particular type of systematic review that focuses on numerical results

... a statistical technique for combining the results of independent, but similar, studies to obtain an overall estimate of treatment effect

Aim: To combine the results from individual studies to produce, where appropriate, an estimate of the overall or average effect of interest, e.g. the risk ratio (RR)

Protocols for the reporting of meta-analysis (to standardise the methods of reporting a meta-analysis), e.g.:

- QUORUM (Quality of Reporting of Meta-analyses)
- MOOSE (Meta-analysis Of Observational Studies in Epidemiology)
- PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)



Example

➔ Ovarian cancer and smoking: individual participant meta-analysis including 28 114 women with ovarian cancer from 51 epidemiological studies

Collaborative Group on Epidemiological Studies of Ovarian Cancer*

Summary

Background: Smoking has been linked to mucinosa

and on overall ovarian cancer risk are unclear, and

To answer these associations, we review the published

literature. Individual participant data for 28 114 women

studies were analysed centrally, yielding adjusted

never smokers.

Findings: After exclusion of studies with hospital or

ovarian cancer incidence was only slightly increased

(RR 1.06, 95% CI 1.05-1.11, $p=0.01$). Of

mucinous, 2560 (73%) endometrioid, 969 (5%)

substantially across these subtypes ($p_{\text{heterogeneity}}=0.00$

versus never smokers (1.79, 95% CI 1.65-1.95,

rather than in fully malignant tumours (2-25, 95%

mucinous tumours were only borderline malignant

clear-cell ovarian cancer risk (0.98, 95% CI 0.84-1.14,

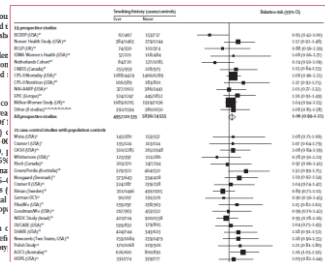
significantly by 13 sociodemographic and personal

and use of alcohol, oral contraceptive, and menopause

Interpretation: The excess of mucinous ovarian

malignancy, is roughly counterbalanced by the deficit

variation in smoking-related risks by tumour subtype



Types of reviews

Review Article

DOI: 10.1111/1471-1842.2009.00848.x

A typology of reviews: an analysis of 14 review types and associated methodologies

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Abstract

Background and objectives: The expansion of evidence-based practice across sectors has led to an increasing variety of review types. However, the diversity of terminology used means that the full potential of these review types may be lost amongst a confusion of indistinct and misapplied terms. The objective of this study is to provide descriptive insight into the most common types of reviews, with illustrative examples from health and health information domains.

Methods: Following scoping searches, an examination was made of the vocabulary associated with the literature of review and synthesis (literary warrant). A simple analytical framework—Search, Appraisal, Synthesis and Analysis (SALSA)—was used to examine the main review types.

Results: Fourteen review types and associated methodologies were analysed against the SALSA framework, illustrating the inputs and processes of each



Review articles: Main types

- Critical review
- Literature review
- Mapping review/systematic map
- Meta-analysis
- Mixed studies review/mixed methods review
- Overview
- Qualitative systematic review/qualitative evidence synthesis
- Rapid review
- Scoping review
- State-of-the-art review
- Systematic review
- Systematic search and review
- Systematised review
- Umbrella review

(Source: Grant MJ & Booth A. 2009. A typology of reviews: An analysis of 14 review types and associated methodologies. *Health Information and Libraries Journal*, 26:91-108.)



Quantitative research

Descriptive	Describe current status of an identified variable or phenomenon	Examples <ul style="list-style-type: none"> • Description of the tobacco use habits of teenagers • Description of the attitudes of scientists regarding global warming
Correlational	Determine extent of a relationship between two or more variables using statistical data	Examples <ul style="list-style-type: none"> • Relationship between diet and anxiety • Relationship between smoking and lung disease
Causal-Comparative/Quasi-Experimental	Establish cause-effect relationships among variables	Examples <ul style="list-style-type: none"> • Effect of an aerobic exercise program on children's rates of obesity • Effect of age on lung capacity
True Experimental	Uses scientific method to establish cause-effect relationship among a group of variables True experiment is where an effort is made to identify and impose control over all other variables except one Include laboratory experiments.	Example <ul style="list-style-type: none"> • Effect of a new treatment plan on breast cancer • Comparison of the effect of Western medicine versus complementary medicine on headache prevalence in a community

(Source: Adapted from https://www.bcps.org/offices/lis/researchcourse/develop_writing_method_quantitative.html)



Examples of study designs

Observational OR Experimental

- **Cross-sectional study** (also known as a *prevalence study*)
 - Observational study
 - Involves analysis of data collected from a population, or a representative subset (a sample)
 - At one specific point in time
- **Longitudinal study**
 - Observational study
 - Several observations of the same subjects are conducted over a period of time, sometimes lasting many years



Examples of study designs (Cont)

- **Cohort studies**
 - Cohort = group that shares the same characteristics among its members
 - Used to investigate the causes of disease, establishing links between risk factors and health outcomes
 - Usually forward-looking (prospective studies), or planned in advance and carried out over a future period of time
- **Case-control studies**
 - Compare patients who have a disease or outcome of interest (**cases**) with patients who do not have the disease or outcome (**controls**)
 - Retrospectively compare how frequently the exposure to a risk factor is present in each group to determine the relationship between the risk factor and the disease



Sampling

- Population or a sample?
- **Probability Sampling** – Uses randomisation & takes steps to ensure all members of a population have a chance of being selected
Examples:
 - Random sampling, Stratified sampling, Systematic sampling, Cluster random sampling, Multi-stage random sampling
- **Non-probability Sampling** – Does not rely on the use of randomisation techniques to select members. Typically done in studies where randomisation is not possible in order to obtain a representative sample. Bias is more of a concern with this type of sampling.
Examples:
 - Convenience or accidental sampling, Purposive sampling, Modal instance sampling, Expert sampling, Proportional and non-proportional quota sampling, Diversity sampling, Snowball sampling



PHARMACOEPIDEMOLOGY

“Pharmaco” + “epidemiology”
= study of the use of and the effects of drugs in large numbers of people
= interactions between drugs and populations

- Borrows its *focus* of inquiry from clinical pharmacology
- Borrows its *methods* of inquiry from epidemiology



Applies methods of epidemiology to content area of clinical pharmacology



Need to know ...

- Epidemiological study designs
 - Ecological studies, cohort studies, case-control studies, case-crossover studies...
- Epidemiological terminology
 - Prevalence, incidence, exposure, outcomes, relative risk, odds ratio, bias, confounding ...



PHARMACOECONOMICS

- Evaluation of the medico-economic consequences attributable to the use of a drug
- Study designs:
 - Cost-effectiveness (CE)
 - Cost-benefit analysis (CBA)
 - Cost-minimization (CM)
 - Cost utility (CU)
- Economic modelling



PHARMACOVIGILANCE

- Detection, evaluation, understanding and prevention of Adverse Drug Reactions (ADRs) (previously: post-marketing surveillance)
- Aim: To optimise the risk-benefit ratio of marketed drugs at the individual or population level



- Side effect = unintended effect of a drug
- ADR = unintended and noxious effect



EVIDENCE-BASED MEDICINE (EBM)

- Conscious, explicit & judicious use of current best evidence in making decisions about individual patients
- Integrates individual clinical expertise with best available external evidence from systematic research

What Is Evidence-Based Medicine?



Sackett DL, et al. BMJ. 1996;313(7021):71-72



CONCLUSION AND RECOMMENDATIONS

- Opportunities for research and collaboration
- Cross-national comparisons (CNCs)
- Research:
 - Consumer studies, impact on quality-of-life of patients
 - Diagnoses and sequential care
 - Dosages
 - Concurrent medication, including alternative therapies
 - Ethics: Pharmacotherapy as a "human right", economic determinants, misuse, abuse, dependence and addiction

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