

RESEARCH



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Overview of study designs I

Observational descriptive studies

Part 1:

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**Please note that just underlined
words were mentioned by the doctor.**

Part 1

Descriptive studies

Study design: Definition

A study design is a specific plan or protocol for conducting the study, which allows the investigator to translate the conceptual hypothesis into an **operational** one.

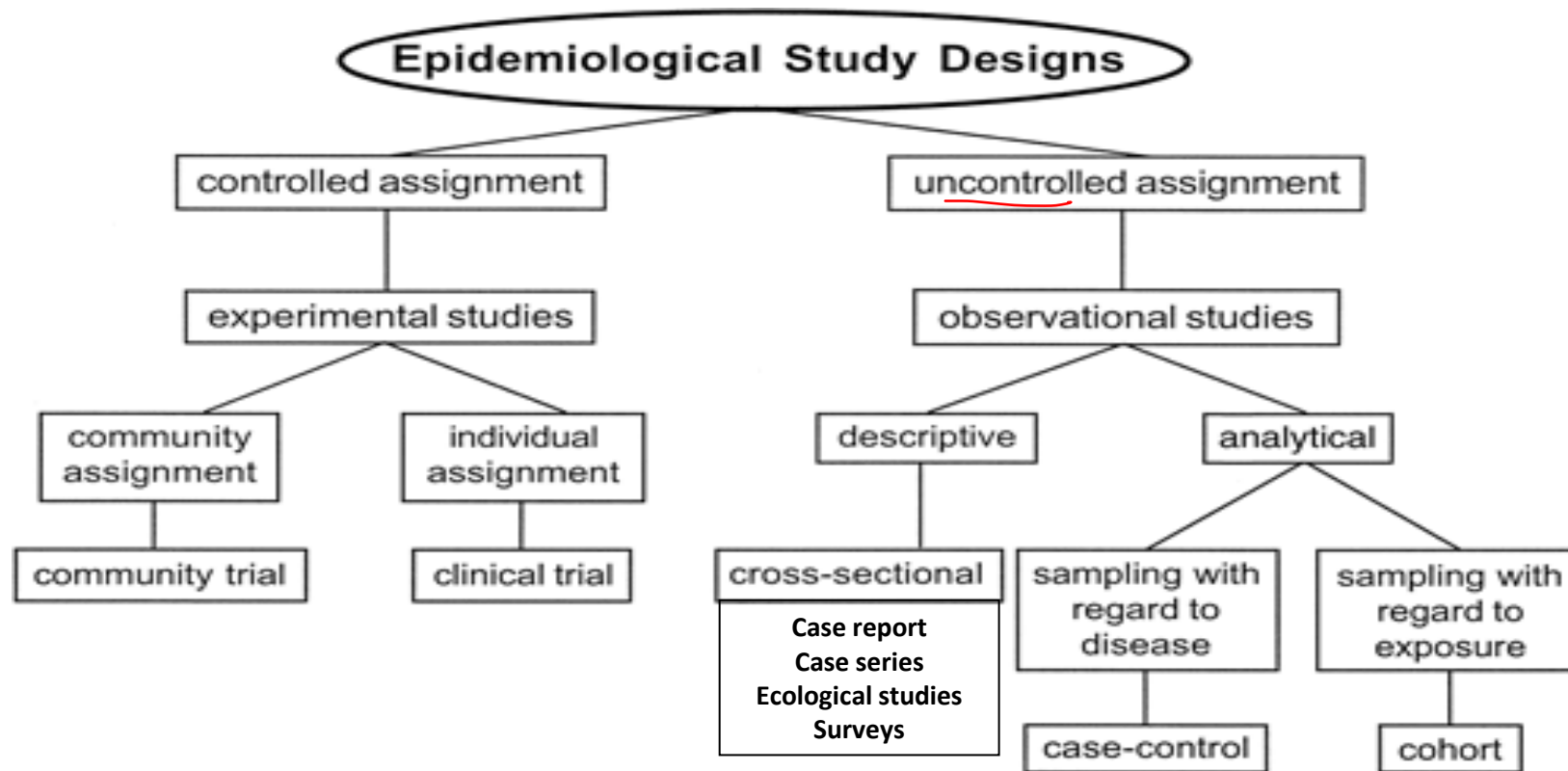
Part of the plane as an example:

We want to study the prevalence of DM → cross sectional study.

New intervention of DM → clinical trial.

Risk factors of DM → cohort study.

اتخاذ هيكل قرارات جزء من ال design.



Very important

Source: Waning B, Montagne M: *Pharmacoepidemiology: Principles and Practice*: <http://www.accesspharmacy.com>

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Controlled assignments :

We do interventions, here are some examples:

**✿ 2 groups of patients , g.1 → taking aspirin
g.2 → taking placebo**

✿ Patients with severe low back pain :

G.1 → seen by physiotherapist every 28 hours

G.2 → seen by physiotherapist every 2 weeks

After 6 weeks we compare the outcomes of both groups.

Note that here we compare group with early referral and group with late, it's not always drugs.

✿ Newly diagnosed DM patients :

G.1 go to primary health care

G.2 go to medical clinics

After a year we compare between them.

✿ Newly diagnosed DM patients :

G.1 1st seen by family physician

G.2 1st seen by general practitioner

After a year we compare between them.

Clinical trials have 2 faces , treatment and prevent let's take examples on them:

Ex: aspirin given to group of people -who don't have colorectal cancer- in order to prevent colorectal cancer, this is preventable type of clinical trial.

Ex: 300 patients with DM , group 1 are taking treatment type 1, while group 2 are taking treatment type 2, this is treatment type of clinical trial.

Community trials here we deal with a community not a group that we chose, examples :

✿ study to improve research

G.1 students at university of Jordan, we give them lectures and workshops on research.

G.2 students at university of Madaba we give them leaflets, posters and videos about research.

After 1 year we compare student's willingness for research.

Note that here we didn't randomised groups specifically by our choice, we are dealing with part of the community (students).

✿ study to see the relation bet chloride and dental cares,

G.1 → we raise chloride levels in water supplements for Aqaba.

G.2 → water supplement in Madaba were kept normal.

After 5 years we compare number of people visiting dentists, note that we are dealing with the community.

Uncontrolled assignment, just observation examples :

✿ **Ex: Aspirin as a risk factor for colorectal cancer, we look at the pharmacy records,**

G.1 take aspirin for a reason, not for colorectal cancer prevention.

G.2 don't take aspirin.

Then we compare, as an example g.1, 30% have cancer while g.2, 2% have, so aspirin is a risk factor.

Descriptive study, it describes something, examples :

> **cross sectional study is a special type of survey, in it we discover the burden, prevalence and the magnitude of the disease.**

✿ **Ex : we want to make an uncontrolled study on DM, we take samples from north, south, middle.....finally we have 10,000 person, we start the study by asking the if they have DM or not, 1000 answered yes [known group], and we do a test (glucose function test) because there may be people have DM and they don't know, 500 person give + to DM from the test, so we have 3 groups, [don't have DM, have and know, have and don't know].**

Prevalence = $1000 + 500 / 10,000$,,,, will equals 15%.

We have 2 types of prevalence, point prevalence & period prevalence, if samples were taken at the same day and prevalence was calculated at the same time this is point prevalence, if it was for example between September & January it is period prevalence.

Ecological study (will be discussed later) just a brief info about it, it deals with the bodies of knowledge (world bank, WHO....) they have info about a lot of diseases and it's correlations such as malnutrition , cold places , bacterial....

✿ **Ex: countries with high meat consumption, has high incidence of colorectal cancer, while countries with low meat consumption has low colorectal cancer, so this lead us to a clue.**

Observational epidemiology

Descriptive → generate hypothesis

Analytical → analyse the hypothesis

reactions

- Provides information about disease patterns or drug use problems by various characteristics of person, place, and time.
- It also is used by epidemiologists to generate hypotheses regarding the causes of disease or drug use problems.

Observational epidemiology

a. Descriptive

Case reports and case series

Descriptive analysis (Person place time)

Ecological (correlational)

Cross-sectional

b. Analytical

Case Control **If I want to study risk factors of a rare disease.**

Cohort **If I want to understand the burden, magnitude of rare disease.**

Cohort deals with incidence not prevalence.

Let's differentiate bet cohort and case control

Cohort

here we make 2 groups one with a risk factor and the other without,

✿ **Example : Cohort study to discover if smoking is a risk factor for DM**

G.1 smokers , G.2 non-smokers,

It's important to make sure all the participants follow the base line, our base line here is that the participant hasn't DM and has a normal glucose function test, otherwise results will not be valid.

G.1 incidence of DM is 20%per year, while G.2 is 5% per year, so smokers has 4 times more risk to DM develop than non-smokers.

Please note that we can study the incidence of more than 1 disease, while having just 1 risk factor in cohort study, in this example we can also study the incidence of cancer, hypothyroidism.....

In case of a rare disease, to do cohort we need a huge sample , because incidence is very low, so we will use case control.

Case control

We get patients who are already have a disease (rare one) and we follow them up.

✿ **Ex: babies were born with congenital heart disease in 2022 in X hospital, this is our sample, we start to search about the risk factors to this rare event, we ask their mothers about drugs we took, age,husband's age,....., then on odds ratio we decide if it correlates or not.**

Please note that we can study many risk factors for 1 disease in case control studies, not as cohort.

It's better to start always with the rare, if you have rare symptoms do cohort, if you have rare disease do case control.

Epidemiological studies

- Observational studies are descriptive or analytical in nature.
- Descriptive studies attempt to uncover and portray the occurrence of the condition or problem, whereas analytical studies determine the causes of the condition or problem.
- Investigators in observational studies may plan and identify variables to be measured, but human intervention is not a part of the process.
- Experimental studies, in contrast, involve intervention in ongoing processes to study any resulting change or difference.

It's make sense, because how to improve a country's health without knowing the what illnesses are there or the risk factors.

Observational epidemiology

- 1. Prevalence of illness**
- 2. Prevalence of risk factors**
- 3. Complication rate of illness**

- Descriptive studies: provide insight, data, and information about the course or patterns of disease or drug use problems in a population or group.

We know the risk factors for DM, but which from them are in the population of interest.

Good to study risk factors.

- Analytical studies are used to test cause–effect relationships, and they usually rely on the generation of new data.

Case Reports and Case Series

✿ **Ex: you have had a rare surgery, the patient has a rare problem after it, was the surgery the cause or a risk factor for the problem?**

Case report is a detailed report by one or more clinicians of the profile of a single patient.

Example: 1961; pulmonary embolism 5 weeks after use on oral contraceptive.

Question: Are women who develop pulmonary embolism more likely to have used oral contraceptives than women who did not develop the disease?

Case Series describes the characteristics of a number of patients with a given disease.

Application: Routine surveillance activities (accumulated case reports). Striking clustering of cases may suggest emergence of new diseases or epidemics

✿ **Ex: prof. Hanson had 20 cases with cervical cancer, 17 of them were HPV+, later he discovered that HPV is a risk factor for the cancer and he got nobel prize.**

✿ **Ex: 10 ladies take oral contraceptives, 2 of them have pulmonary embolism.**

Case report and case series

in case series

- Clinician finds unusual features of a disease or effects of a drug, or the patient's medical history, that lead to the formulation of a new research question or hypothesis

Imagine a clinical study,

G.1 → take new treatment of DM, 300 patients.

G.2 → take the standard treatment.

After comparing, G.1 has less side effects, so we generalised the new drug, but it seems that the drug cause renal impairment 1 in each 10,000, so this dangerous side effect can't be discovered at Case report, series, we see it just when the number of patients has increased.

This is an example, the doctor didn't read it, but he said it's better for you to read.

Hammade *et al.*
Journal of Medical Case Reports (2022) 16:386
<https://doi.org/10.1186/s13256-022-03630-1>

Journal of
Medical Case Reports

CASE REPORT

Open Access

Isolated giant renal hydatid cyst with a simple renal cyst appearance: a case report



Mohammed Hammade^{1*} , Sami Alhoulaiby¹ and Adnan Ahmed²

Abstract

Background: Isolated renal hydatid cysts of the kidney are a rare occurrence that account for about 2–3% of all hydatidoses. They can stay asymptomatic for years and could have a variable presentation on imaging techniques, which results in a challenging diagnostic process.

Case presentation: We report a 22-year-old Caucasian male with a large cyst on the upper pole of the left kidney that had no septations nor membrane calcifications on computed tomography, which led to mistakenly considering it a simple renal cyst. The true diagnosis was identified intraoperatively and proven postoperatively by pathology.

Conclusions: This case highlights the importance of keeping echinococcosis in mind when treating suspected renal cysts and tumors to avoid incorrect treatment and possible content spillage, anaphylaxis, and peritoneal dissemination.

Keywords: Isolated renal hydatid cyst, Renal echinococcosis

Case Reports Case Rep Neurol

. 2017 Mar 20;9(1):44-48. doi: 10.1159/000460814. eCollection 2017 Jan-Apr.

A Case Report of Severe Delirium after Amantadine Withdrawal

Franz Marxreiter 1, Jürgen Winkler 1, Martin Uhl 2, Dominik Madžar 2

Affiliations expand

PMID: 28611642 PMCID: PMC5465776 DOI: 10.1159/000460814

Free PMC article

Abstract

Amantadine is frequently used in addition to dopaminergic substances like dopamine agonists or L-Dopa in advanced Parkinson disease (PD). However, adverse effects like hallucinations limit its use. PD patients developing severe psychotic symptoms upon treatment with either dopaminergic substances and/or amantadine need to stop intake of any psychotropic substance. Here, we report the case of a 71-year-old PD patient without previously known cognitive impairment. He presented with drug-induced psychotic symptoms due to changes in his therapeutic regimen (increase in COMT inhibitors, newly introduced MAO B inhibitor). Also, amantadine had been part of his long-term medication for more than 2 years. The severity of his psychotic symptoms required a L-Dopa monotherapy. After changing his medication, the patient developed severe delirium that resolved rapidly after i.v. amantadine infusion, suggesting an amantadine withdrawal syndrome. Amantadine withdrawal syndrome is a rare adverse event that may present even in PD patients without cognitive impairment. This case report highlights the need for a gradual withdrawal of amantadine even if acute and severe psychotic symptoms are present. Moreover, this is the first report of a cognitively unimpaired patient developing an amantadine withdrawal syndrome.

Keywords: Amantadine; Amantadine withdrawal; Delirium; Parkinson disease; Psychotic symptoms.

Understand don't memorise

In case report, series, start with an introduction about the drug/disease, the side effects, your case, discuss manifestations, previous studies and finally your recommendations.

Case Reports Transpl Int

. 2002 Jul;15(7):374-6. doi: 10.1007/s00147-002-0426-9. Epub 2002 Jun 20.

Colchicine myoneuropathy in a renal transplant patient

Peter Dupont 1, Ian Hunt, Lawrence Goldberg, Anthony Warrens

Affiliations expand

PMID: 12122515 DOI: 10.1007/s00147-002-0426-9

Abstract

Colchicine is widely employed for the treatment of gout in renal transplant patients where NSAIDs are contra-indicated and allopurinol prophylaxis is often avoided due to concomitant azathioprine immunosuppression. We report here a case of colchicine-induced myoneuropathy in a renal transplant recipient. Our patient had myalgia, muscle weakness, elevated creatine kinase levels, myopathic changes on electromyography and peripheral neuropathy. Withdrawal of colchicine resulted in recovery within 4 weeks. Renal transplant recipients are likely to be at greater risk of colchicine-induced myoneuropathy due to the unique concurrence of risk factors predisposing to toxicity in such patients. These risk factors include the high incidence of gout in this population, widespread use of colchicine as first-line therapy, impaired renal function and concomitant cyclosporin treatment. The diagnosis should be considered in any renal transplant recipient receiving the drug who develops myopathy. Prompt withdrawal of colchicine therapy should result in rapid clinical and biochemical improvement.

PubMed Disclaimer

Case reports

- The most common type of study published in the medical literature. [Dr. didn't say it, but it's special like u]
- They note unusual medical occurrences, identify new diseases, and describe adverse effects from drug therapies.
- Clinical investigators can use challenge–rechallenge data to help establish causality.
- In this approach, administration of a drug (the challenge) might be suspected of producing a specific symptom (side effect or adverse reaction).
- Administration of the drug can be stopped to observe whether the side effect or adverse reaction diminishes. (This is the challenge-re challenge)
- If it does, then administration of the drug can be resumed (the rechallenge) to observe whether the effect returns, suggesting a possible relationship between the two events.

Case-series:

Clinical case series

- Usually a coherent and consecutive set of cases of a disease (or similar problem) which derive from either the practice of one or more health care professionals or a defined health care setting, e.g. a hospital or family practice.

**Here we have patients and we follow them → we look for their quality of life, complication rate.....
keep in mind that we have all of their information.**

✿**Ex: Acute onset of colchicine myoneuropathy in cardiac transplant recipients: case studies of three patients**

Author links open overlay panel Sandeep S Rana a, Michael J Giuliani a, Chester V Oddis b, David Lacomis a c

Abstract

Colchicine causes both muscle and peripheral nerve toxicity of subacute onset in patients with renal insufficiency. We report three cardiac transplant recipients, treated with colchicine for cyclosporin A (CyA)-induced gout, who developed acute weakness due to colchicine myoneuropathy. The onset of disabling weakness occurred over a 1–2 week period. All three patients had concomitant renal insufficiency and an elevated serum creatine kinase and two had elevated CyA levels at the time of presentation. Electromyography revealed features of myopathy and motor axonal neuropathy in all three patients. Two underwent muscle biopsy which confirmed the presence of sarcoplasmic vacuoles characteristic of colchicine-induced myopathy. All patients rapidly improved with either colchicine dose reduction or drug discontinuation. (challenge- re challenge) In conclusion, cardiac transplant recipients treated with CyA and colchicine may be at increased risk of developing colchicine-induced myoneuropathy especially in the setting of concurrent renal insufficiency. In patients with post-transplantation gouty arthritis, other treatment modalities are suggested; and if colchicine is administered, the dose should be reduced, CyA levels should be monitored closely and patients should be assessed for signs of neuromuscular toxicity.

CASE REPORT

Open Access



Ex: Syrian females with congenital adrenal hyperplasia: a case series



Nada Dehneh^{1*}, Rami Jarjour^{2,3}, Sahar Idelbi⁴, Assad Alibrahem^{4,5} and Sahar Al Fahoum¹

Abstract

Background: One of the most common types of congenital adrenal hyperplasia is an autosomal recessive disorder with 21-hydroxylase deficiency. The classical form, defined by cortisol insufficiency, is accompanied by prenatal androgen excess causing variable masculinization degrees of external genitalia in babies with a 46, XX karyotype.

Cases presentation: These five case reports highlight the management of Syrian females aged between 0 and 32 years with congenital adrenal hyperplasia. Two of the patients have been raised as males, while two had reconstructive surgery and one had hormonal therapy. Becoming mother was achieved by two patients

Conclusion: The integrated treatment of females with classical congenital adrenal hyperplasia CAH, which includes appropriate surgical procedures and controlled hormonal therapy, gives these females the opportunity to live as they are, and perhaps as mothers in the future.

Keywords: Congenital adrenal hyperplasia, Syria, Case report

Case-series:

Clinical case series

- A case-series is, effectively, a register of cases.
- Analyse cases together to learn about the disease.
- Clinical case-series are of value in epidemiology for:
 - Studying symptoms and signs
 - Creating case definitions
 - Clinical education, audit and research

Remember our example, newborns with CHD, and we follow them to understand the characteristics of their disease.

Case series: Natural history and spectrum

- **Helps professionals can build up a picture of the natural history of a disease**

🍀 **Ex: Cystic fibrosis patients, we follow them to figure out how to improve their outcome.**

Case series: Natural history and spectrum

- **Population case-series is a systematic extension of this series but which includes additional cases, e.g. those dying without being seen by the clinicians.**
- **Add breadth to the understanding of the spectrum and natural history of disease.**

Case series: Limitations

You study 4,5 patients in 1 hospital, there are a lot outside.

Usually we cannot estimate the prevalence or incidence rate

- Breast cancer registry in Jordan: We cannot provide prevalence rates without:

1. Population size
2. Time- period of data collection
3. All cases of breast cancer are registered

We have 1 exception , we can calculate the incidence in case series only if we have data of all the population, this occurs when the country's law is to register any new case of the disease of interest of our study.

Exception for calculation of the incidence: Jordan National Cancer registry can generate data on the incidence.

All cancer cases in Jordan are reported to the Registry office.

No control group for comparison

Note the law was established in 1997 and it has been applied on basherAl-bashir hospital only,there was 300 patients,in 2000 all government hospitals were included,there was 500 patients ,in 2005 military and private hospitals were included,there was 700 patients, in 2022 there was 1000 patients,our point here is that it's wrong to say that the incidence increased from 1997 to 2022 by 3 times, because not all hospitals were included, you can compare 2005 with 2022 just, because they have the same circumstances.

✿Ex: 20 cases have hypothyroidism, 15 of them are smokers, here you can't compare because smokers in general population have high percentage.

Case series: Population

- **Case-series can provide the key to sound case control and cohort studies and trials**
- **Design of a case-series is conceptually simple**
- **Defines a disease or health problem to be studied and sets up a system for capturing data on the health status and related factors in consecutive cases**

✿Ex:

Congenital Rubella Syndrome: The classic description of a series of infants born with congenital cataracts, some with additional cardiac abnormalities, in Australia in 1941.

This led Gregg in Sydney to postulate a causal link between a severe epidemic of rubella that had occurred six to nine months before the children were born and the subsequent abnormalities.

It is now well known that if a woman develops rubella during pregnancy it may affect her unborn baby.

CASE REPORT

Open Access

Syrian females with congenital adrenal hyperplasia: a case series



Nada Dehneh^{1*}, Rami Jarjour^{2,3}, Sahar Idelbi⁴, Assad Alibrahem^{4,5} and Sahar Al Fahoum¹

Abstract

Background: One of the most common types of congenital adrenal hyperplasia is an autosomal recessive disorder with 21-hydroxylase deficiency. The classical form, defined by cortisol insufficiency, is accompanied by prenatal androgen excess causing variable masculinization degrees of external genitalia in babies with a 46, XX karyotype.

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Disease registry

Definition of Registry

✿ **Ex: registration for cancer in hospital x, we put the names and all the information of the patients with cancer , symptoms, drugs....**

we make a follow up to → quality of life, complication rate.....

So we understand what really happen to the patient.

- The term *registry* is defined both as the act of recording or registering and as the record or entry itself.

Patients must approve, no interventions are done, it's observational study.

- Therefore, “registries” can refer to both programs that collect and store data and the records that are so created.

- **Special form of case series**

If 2 hospitals give different treatment to same disease, you can compare the outcomes by the registry data.

Disease Registry

- Patient registries have been defined as:

“an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s).”

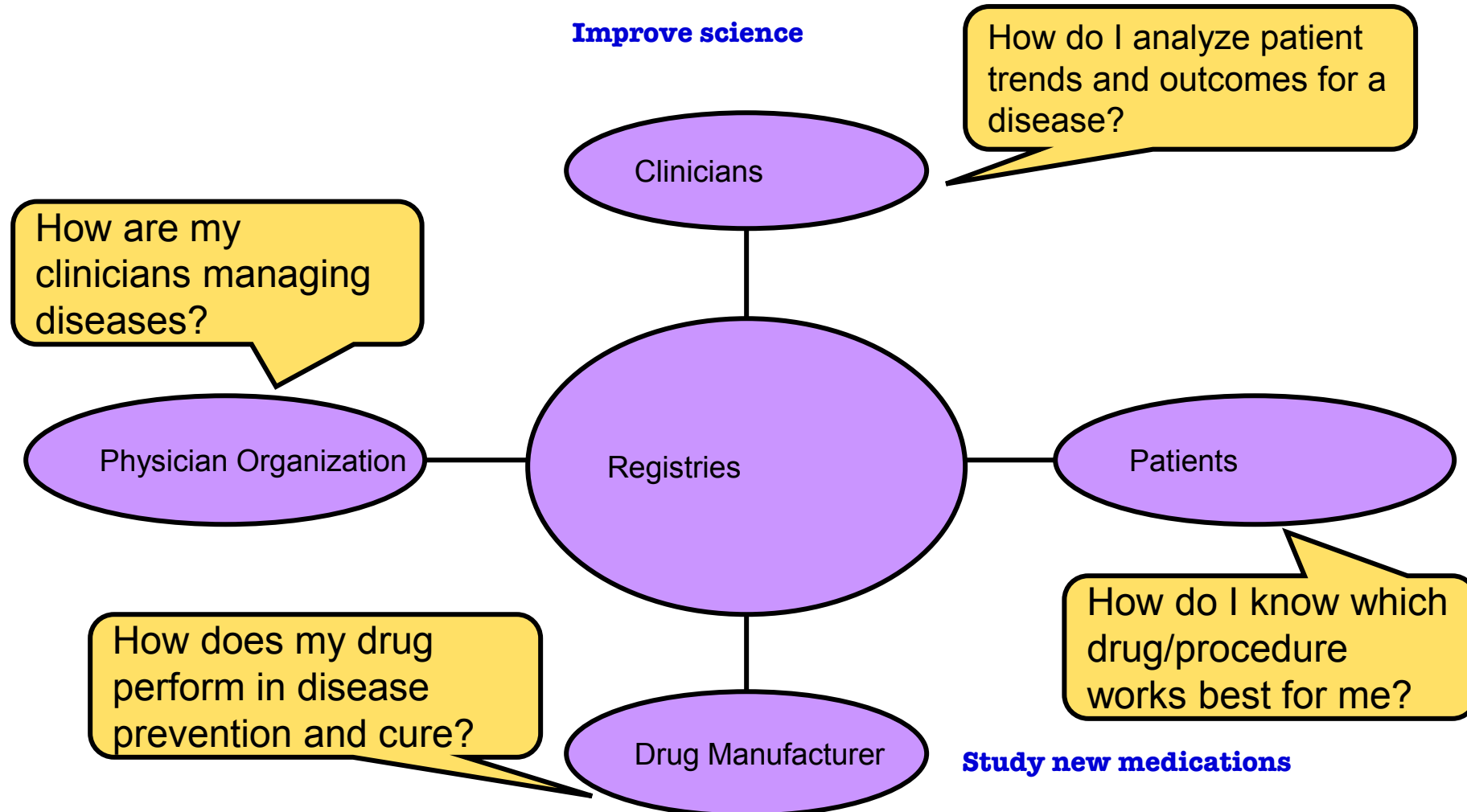
Traditional Patient Registries

Also an advantage, I can include patients with registry information in clinical trials, I already know all the information about them.

- The purposes for patient registries can range widely.
- **According to the National Institutes of Health:**
- “Registries can be used to recruit patients for clinical trials, to learn about a particular disease or condition; to develop therapeutics or to learn about population behavior patterns and their association with disease development; developing research hypotheses; or for improving and monitoring the quality of health care.”

Varying Benefits

The words in the figure were mentioned by the doctor



Real World Evidence Analysis

- Customized Real World Evidence Analysis: Application and treatment results of various drugs in clinical routine
- **REAL WORLD EVIDENCE** Analysis – Analysis of defined patient cohorts under “real life” conditions (including all comorbidities, AEs & SAEs incl.)

If we want to make a clinical trial for DM, there are many inclusion & exclusion criteria, patients with registry are specific for this study [DM can be affected by comorbidities, which are written in the registry], but the results will fit just people with similar circumstances, so we need REAL WORLD EVIDENCE.

Quality Improvement

- How do we know a change is needed?
- How do we know a change is an improvement?
- How do we know where to put scarce resources?

A Disease Registry can provide data to:

- Describe the patient population
- Identify patient sub-groups having the most need
- Identify who is in the sub-groups
- Show the 'reach' of intervention programs
- Show the outcomes of intervention programs
- Pharmacovigilance: supports reporting of ADRs

Remember that registry are case series so they are observational, no interventions.

Types of Registries

■ Mortality registry

- An important thing to know about your patients

■ Research Patient Registry

- Clinical Trials

■ Disease or Condition Registries

- Disease or condition registries use the state of a particular disease or condition as the inclusion criterion.
- One disease or group of diseases: Cancer registry, multiple sclerosis registry, bleeding disorders.

■ Service, intervention, device registry

BMT registry, Biosimilars registry

Coverage

Except 1 case

- Hospital or clinic based: Do not use for calculating incidence
- Local
- Regional
- National: Excellent for calculation of incidence if there is a valid and reliable surveillance system in place.
- International

Question for discussion: how can we collect data for the above types of registries?

Registries VS. RCT's

These definitions are from me, but the idea- that we use efficacy for control trials, and effectiveness for observational- were mentioned by the doctor.

- RCT (**Randomised control trials**)

- Best for assessment of therapeutic efficacy

Pay attention to the words

Efficacy : the degree of successful , under controlled circumstances - comparing with a placebo group.

- Registry

- Therapeutic effectiveness (Just observing)
- Safety/harm of therapy
- Generalizability to populations

Effectiveness : how well it performs in the real world.

- **Key Difference**

- Registries do not randomize

Uses for Patient Registries

- To observe the course of disease (natural history)
- To understand variations in treatment and outcomes
- To examine factors that influence prognosis and quality of life
- To describe care patterns, including appropriateness of care and disparities in the delivery of care
- To assess effectiveness
- To monitor safety

Components of disease registry

- Personal Domain
- Exposure Domain
- Outcomes Domain

The personal domain

- Consists of data that describe the patient, such as information on patient demographics, medical history, health status, and any necessary patient identifiers.

The exposure domain

- Describes the patient's experience with the disease, medication, device, procedure, or service of interest to the registry.
- Exposure can also include other treatments that are known to influence outcome but are not necessarily the focus of the study, so that their confounding influence can be adjusted for in the planned analyses.
- Baseline assessment and storage of samples (for future)

We call it bioback

The outcomes domain

- Consists of information on the patient outcomes that are of interest to the registry
- This domain should include both the primary endpoints and any secondary endpoints that are part of the overall registry goals.

Look at → survival, complication rate.....

Current Trends Measuring Quality Using Registries

- Quality-focused registries are being used increasingly to assess differences between providers or patient populations based on performance measures that compare:
 - Treatments provided or outcomes achieved with “gold standards” (e.g., evidence-based guidelines)
 - Comparative benchmarks for specific health outcomes (e.g., risk-adjusted survival or infection rates)
- Role of health information systems

Hakeem application is an example of registry.

Quality Management Reporting - Example

	Eligible	Satisfied	Rate
Preventive Services			
Cervical Cancer Screen	223	146	65%
Mammogram	138	83	60%
Colorectal Cancer Screen	355	143	40%
Pneumonia Vaccine	144	33	23%
Osteoporosis Screened or on Treatment	75	44	59%
Cardiovascular Disease			
HTN: good BP control (mean or last \leq 140/90)	310	196	63%
CAD: antiplatelet medication	62	54	87%
CAD: lipid lowering medication	65	54	83%
CAD: Beta blocker post-MI	12	10	83%
CAD: ACE/ARB if DM or LVSD + CAD	25	19	76%
CHF: anticoagulation for AF + HF	6	5	83%
CHF: ACE/ARB if LVSD	3	3	100%
CHF: beta blocker if LVSD	3	3	100%
Diabetes			
Last Hba1c \leq 7	87	37	43%
Last Hba1c \leq 9	87	66	76%
Good BP control (mean or last BP \leq 130/80)	83	39	47%
Good LDL control ($<$ 100)	87	49	56%
Nephropathy: screened or on ACE/ARB	87	64	74%

Getting the Most Out of Your Disease Registry

Which cause more the cure or the prevention?

- Cost effective & treatment efficacy
- Feedback reports to physicians about their care practices
- Process improvement projects for service line clinical programs
 - Use trend analysis to find possible process deficiencies that affect patient care
- Population reporting and analysis for research (e.g. Epidemiology)