MFDS / MJDF · RESEARCH AND EVIDENCE

Evidence-Based Practice

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EXAM-DAY SUMMARY

everything on this page → detail in §§ overleaf

DEFINITIONS & TAXONOMY → §1

- Hypothesis = testable explanation of an observation; null hypothesis = the opposite
- Descriptive = case report · case series · cross-sectional survey
- Analytical = cohort · case control; Experimental = RCT
- Primary = RCT/cohort/case control; secondary = SR, meta-analysis, guidelines

LEVELS OF EVIDENCE → §1

- L1 guidelines · meta-analysis/SR · RCT
- L2 cohort (prospective) · L3 case control (retrospective)
- L4 case report/series · L5 narrative review, expert opinion, editorial
- Base = animal & laboratory studies — no humans

RCT — WHAT & WHO → §2

- Gold standard for therapeutic evaluation; compares treatments or strategies
- Components: participants (patient) · investigator (doctor) · control group · intervention group
- Control = conventional intervention / conventional drug / placebo / no treatment

RCT DESIGNS → §2

- Parallel: one intervention only — drug or placebo
- Cross-over: both interventions in random order → patient satisfaction
- Split-mouth: patient is own control, side randomised; ✗ for two mouth rinses, ideal for implants
- Double dummy: tablet + placebo injection vs injection + placebo tablet

STIPULATIONS OF AN RCT → §3

- Randomisation (computer sequence, coins, random-number tables, birthdates)
- Blinding: double = investigator + participant; triple = + statistician; single where surgeon must know
- Inclusion/exclusion criteria · sample size (cost, prevalence, variables)
- Follow-up: worst-case outcome to those lost; loss > 20% unacceptable
- Internal validity = design/conduct/analysis; external = generalisability

RCT NUMBERS → §4

- Example: benefit 60 vs 80 per 100; risk 40 vs 20
- ARR = 80 − 60 = 20% absolute risk reduction
- NNT = 1/ARR = 1/0.20 = 5
- RR = intervention risk ÷ control risk = 20/40 = 0.5; 1 = no difference, <1 new drug better, >1 worse

PHASES & EFFICACY → §5

- Ph1 animal → healthy volunteers: safety + dose; Ph2 patients: efficacy
- Ph3 vs conventional drug: effectiveness; Ph4 monitoring = survey, not RCT
- Efficacy = works in those who *receive*, strict criteria, investigator-controlled (Ph2)
- Effectiveness = works in those to whom it is *offered*, less strict (Ph3)

REVIEWS & META-ANALYSIS → §6

- SR = pre-specified protocol, multiple RCTs identified · appraised · summarised
- Qualitative alone, or quantitative = meta-analysis (statistical combining of results)
- Narrative: broad question, no protocol, no search strategy, no criteria → high bias

CROSS-SECTIONAL & RATES → §7

- Snapshot at one time point; cheap, quick, repeatable, many risk factors; measures prevalence
- ✗ cannot measure incidence or causality
- Prevalence = have it now ÷ all; incidence = new cases over time ÷ population
- Example: 300/500 = 60% prevalence at 10 y; 200/500 = 40% incidence
- Causality: dose response · temporal relation · consistency

COHORT VS CASE CONTROL → §8

- Cohort: prospective, exposure → disease; gives prevalence, incidence, causality
- Case control: retrospective, disease → cause; none of those three
- Cohort ✗ expensive, time consuming, attrition; case control ✗ egg-and-chicken

MEASURES OF ASSOCIATION → §8

- RR = diseased exposed ÷ diseased non-exposed = 70/20 = 3.5; >1 risk, <1 protective
- AR = 70 − 20 = 50% → smoking itself adds 50% of the 70%
- OR = ad/bc; tetracycline example (85×75)/(25×15) = 17; >1 risk, <1 protective

BIAS & PRACTISING EBD → §9

- Bias = selectively choosing evidence to support one's own view: selective · publication · seduction of authority · false idol of technology · financial · let sleeping dogmas lie
- EBD = evidence + clinical skills + patient needs → shared decision-making
- 5 steps: Assess → Ask → Acquire → Appraise → Apply; question = PICO; Boolean AND/OR/NOT
- Therapy → RCT · aetiology → case control · prognosis → cohort; PubMed, Cochrane

§1 Foundations & the hierarchy of evidence

1.1 Starting definitions

Hypothesis

Testable explanation of an observation.

Null hypothesis

The opposite — the statement of no difference/no effect that the study sets out to reject.

1.2 Taxonomy of study designs

Three families, split by what the investigator does to the participants.

Table 1 — The three families of study design

Family	Designs	Investigator controls exposure?
Descriptive	Case report · case series · cross-sectional survey	No — describes only
Analytical	Cohort · case control	No — observes exposure that already exists
Experimental	Randomised controlled trial (RCT)	Yes — allocates the intervention

- **Observational**: descriptive + analytical → investigator watches, never allocates
  - cohort + case control = **non-experimental observational studies**
- **Primary studies**: RCT · cohort · case control → generate new data
- **Secondary studies**: systematic reviews · meta-analyses · clinical practice guidelines → pre-appraised, "filtered" evidence built on primary studies

1.3 Levels of evidence

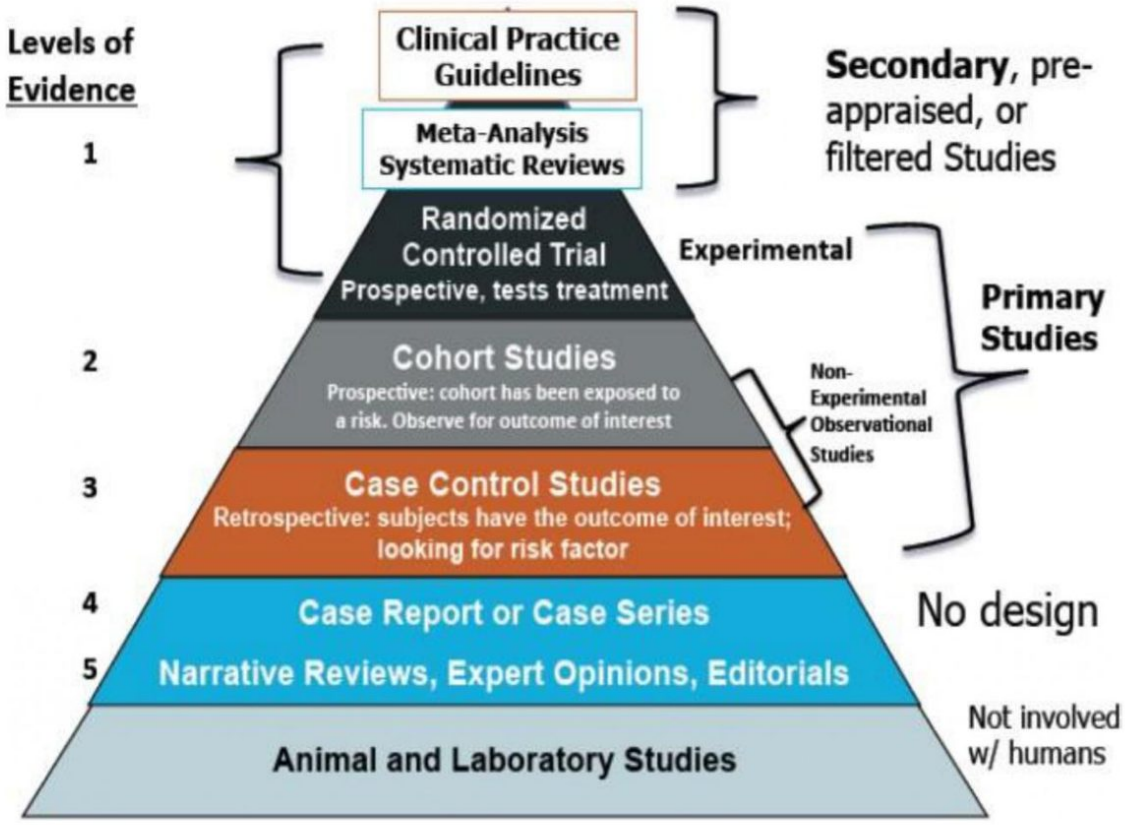

Fig. 1 — Levels of evidence. L1 guidelines + meta-analysis/SR + RCT · L2 cohort · L3 case control · L4 case report/series · L5 narrative review, expert opinion, editorial · base = animal and laboratory studies (no humans).

- **Level 1**: ★**clinical practice guidelines · meta-analysis & systematic reviews · RCT** — secondary/pre-appraised sit above the primary RCT
- **Level 2 — cohort**: prospective · cohort exposed to a risk → observe for outcome of interest
- **Level 3 — case control**: retrospective · subjects already have the outcome → look back for the risk factor
- **Level 4**: case report or case series — "no design"
- **Level 5**: narrative reviews · expert opinions · editorials
- **Below the pyramid**: animal and laboratory studies → not involved with humans

> ★ EXAM PEARL
> The deck contradicts itself on levels 4/5: the pyramid (Fig. 1) puts **case report *and* case series together at level 4**, with narrative review/expert opinion at level 5 — but a later slide splits them as "case report = level 5, case series = level 4". Answer from the pyramid; it matches the conventional hierarchy.

§2 Randomised controlled trials — anatomy and designs

> KEY POINTS
> RCT = **gold standard for therapeutic evaluation** · compares different treatments or different strategies · the only design in which the investigator allocates the intervention.

2.1 Components

- **Participants**: the patients
- **Investigator**: the doctor
- **Control group**: the standard of comparison → conventional intervention · conventional drug · placebo · no treatment
- **Intervention group**: receives the new intervention

2.2 The four designs

Table 2 — RCT designs

Design	What happens	Typical use
Parallel	Participant exposed to **only one** intervention — new drug *or* placebo	Default two-arm trial
Cross-over	Participant given one intervention **then the other**, in random order	Comparing patient satisfaction
Split-mouth	Each patient is **his/her own control**; treatments on different sides; intervention randomised to right or left	Procedural treatment e.g. implant placement
Double dummy	Two **forms** of one medication (tablet vs injection); group 1 = drug tablet + placebo injection · group 2 = drug injection + placebo tablet	Blinding when routes differ

2.3 Cross-over — the denture example

- **Randomisation**: conventional denture *vs* implant-retained denture
- **After the evaluation period**: groups swap
  - conventional-denture arm → receive dental implants + a new or modified denture
  - implant arm → **abutments only removed**, soft tissues heal over the implants (implants "allowed to sleep") → conventional denture made
- **Result**: every patient experiences both interventions → reports satisfaction on both

2.4 Split-mouth — trade-off

- **Advantage**: influence of **host-related factors** reduced → general health · age · oral hygiene equal on both sides
- **Disadvantage**: unusable where the effect cannot be confined to one side
  - classic failing example: ★**comparison of two mouth rinses** → rinse spreads across the whole mouth

> ★ EXAM PEARL
> Split-mouth is chosen for **procedural, site-limited** interventions (implants, restorations, surgical flaps) and rejected for anything that circulates — rinses, systemic drugs. Cross-over, by contrast, controls the patient across *time* rather than across *sides*.

§3 Stipulations & quality of an RCT

Five stipulations; each maps to a way bias would otherwise enter.

3.1 1 · Randomisation

- **Rule**: all participants have the **same chance** of being assigned to each study group
- **Purpose**: groups balanced for disease severity + any other predictor of prognosis → no bias
- **Methods of allocation**: computer-generated sequences · coins · random-number tables · birthdates … etc

3.2 2 · Blinding

Table 3 — Levels of blinding

Level	Who is blind	Note
Single blind	Participants (assessing clinicians blind, operator not)	Used where double blind is impossible
Double blind	Investigators + participants	All groups treated equally apart from the experimental treatments compared
Triple blind	Investigators + participants + **statistician**	Analyst blind to the identification of the study group

- **Why blind**: all patients and clinicians involved blind to the intervention → the only difference between groups is the treatment itself → avoids bias
- **Surgical trials**: double blind not always possible — the surgeon knows which of the alternative techniques he or she is using
  - workaround → ★**clinicians other than the operating surgeon, blind to the study group, carry out the postoperative assessments**

3.3 3 · Inclusion and exclusion criteria

- **Definition**: the criteria that determine who can enter the trial and who should be excluded

3.4 4 · Sample size

- **Rule**: trials large enough to have a **high chance of detecting a benefit** from treatment
- **Factors affecting sample size**: cost · prevalence of the disease · presence of variables

3.5 5 · Completeness of follow-up

- **Rule**: all patients accounted for at the conclusion of the trial
- **Why it matters**: patients may have dropped out **because of an adverse outcome** → losing them flatters the treatment
- **Conservative handling**: assign the **worst-case outcome** to all those lost to follow-up
- **Ceiling**: loss of ★**more than 20% is unacceptable**

3.6 Assessing the quality of an RCT

Internal validity

Degree to which the trial has been designed, conducted and analysed — is the answer true *for this trial*?

External validity

Extent to which it is possible to generalise the results to other settings.

> ★ EXAM PEARL
>
> Tight inclusion criteria and heavy protocol control **raise internal validity but lower external validity** — the same trade-off that separates efficacy from effectiveness (§5).

§4 Analysing an RCT

Table 4 — Worked example: conventional vs new drug

	Conventional drug	New drug
All participants	100	100
Benefit	60	80
Risk (failure)	40	20

- **Absolute risk reduction (ARR)**: the change of risk of a given activity or treatment **in relation to the control**
  - worked: 80 − 60 = ★**20** → the new drug reduces the risk of failure by **20%** (identically, risk 40 → 20)
- **Number needed to treat (NNT)**: how many people need to receive a treatment before **one** person would experience a beneficial outcome
  - formula → ★**NNT = 1 / ARR**; here 1 / 0.20 = **5** patients per extra benefit [arithmetic worked from the lecture's own figures]
- **Risk ratio (RR)**: ratio of the risk in the **intervention** group to the risk in the **control** group
  - RR = 1 → no difference · RR < 1 → new drug more efficient · RR > 1 → new drug less efficient
  - here 20 / 40 = **0.5** → new drug more efficient [worked from the table]

> KEY POINTS
>
> ARR is a **subtraction** of risks (absolute, gives NNT); RR is a **division** of risks (relative, direction only). Same trial, two different-looking numbers — the discriminator is subtraction vs division.

§5 Drug trial phases · efficacy vs effectiveness

Table 5 — Trials designed for evaluation of a new drug

Phase	Subjects	Question answered
Phase 1	Animal studies, then **healthy volunteers**	Safety and potential efficacy; establishment of the appropriate dose level
Phase 2	Human trials with **patients**	**Efficacy** — does it work?
Phase 3	Patients, vs the conventional drug	**Effectiveness** — does it work better than what we already use?
Phase 4	Post-marketing population	Monitoring — ★**not an RCT but rather a survey**

The lecture places animal work inside phase 1; most texts call animal work *preclinical* and reserve phase 1 for first-in-human safety/dose finding. Answer as the lecture states unless the stem separates preclinical.

Table 6 — Efficacy vs effectiveness

	Efficacy	Effectiveness
Question	Does the intervention work in people who **receive** it?	Does it work in people to whom it has been **offered**?
Control of intervention	Completely controlled by the investigator	Not controlled by the investigator
Inclusion/exclusion	Strict criteria	Less strict
Assessed in	Phase 2 RCT	Phase 3 RCT

★ EXAM PEARL

Efficacy = ideal conditions, **compliance guaranteed**; effectiveness = real world, including those who never take it. Effectiveness is always ≤ efficacy — and "offered vs received" is the exact wording examiners use to separate the two.

§6 Systematic review & meta-analysis

- **Systematic review**: a **pre-specified protocol** brings multiple RCTs on a similar topic together
  - primary studies systematically **identified · appraised · summarised** → one summary answer
- **Two flavours**: qualitative alone · quantitative **with meta-analysis**
- **Meta-analysis**: a systematic review that uses a **statistical method for combining the results** of individual studies → a quantitative study
  - every meta-analysis is a systematic review; ★**not every systematic review is a meta-analysis**

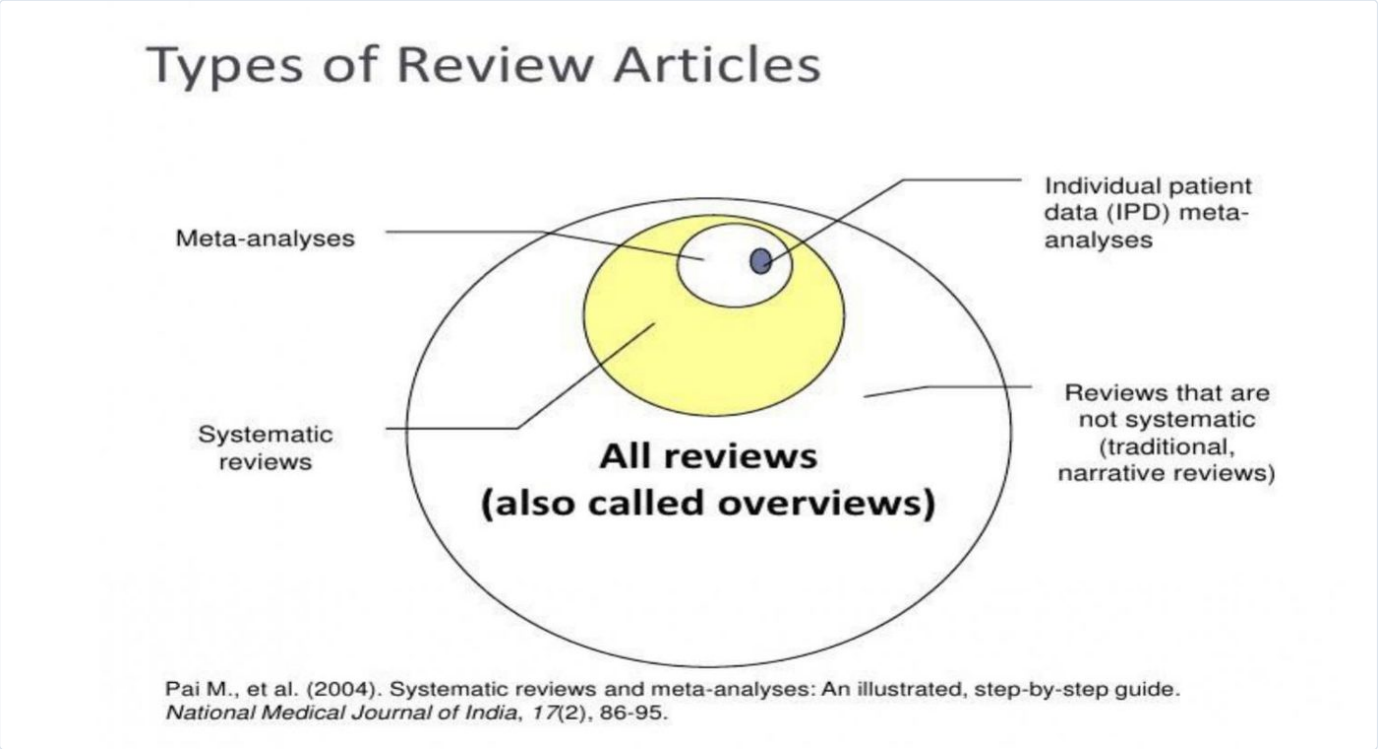

Fig. 2 — Types of review article: all reviews (overviews) ⊃ systematic reviews ⊃ meta-analyses ⊃ individual patient data (IPD) meta-analyses; everything outside the yellow set = traditional/narrative reviews. After Pai M. et al. (2004), *Natl Med J India* 17(2):86–95.

Table 7 — Systematic review vs narrative review

	Systematic review	Narrative review
Research question	Specific	Broad and non-specific
Pre-specified protocol	All steps of the review established in a protocol	No protocol
Objectives	Specified	May or may not be specified
Study inclusion/exclusion	Explicit and specific criteria set	No such criteria
Search strategy	Comprehensive, extensive and systematic	No search strategy
Including studies	Explicit and pre-specified criteria	No criteria set
Data extraction	Systematic and specified	No set rules → **high probability of bias**

§7 Descriptive observational studies

- **Case report**: single patient — no design
- **Case series**: a run of similar patients — no design (deck writes "case serious"; read "case series")
- **Cross-sectional study**: the workhorse descriptive design — below

7.1 Cross-sectional study

- **Purpose**: assess association of a disease to risk factors or any other predictor
- **Timing**: data collected from samples **at one time point** → a **snapshot**
- **Uses**: survey for public health planning · ecological study · ★**measures prevalence**
- **Advantages**: not expensive · not time consuming · repeatable · many risk factors assessed at once · measures prevalence
- **Disadvantages**: results may change in another time frame · ★**cannot measure incidence or causality**

7.2 Prevalence and incidence

Prevalence

Proportion of people who have the condition, out of the whole number of participants, at one point in time → "how many people have the disease **now**?"

Incidence rate

Number of **new** cases through a given time period, per whole population.

- **Where they are used**: ecological studies → monitor population health · develop public health strategies
- **Worked example** — sample of 500 smokers
  - baseline: 100 already have lung cancer · +50 new cases at 5 years · +150 new cases over the following 5 years
  - prevalence at 10 y = all with cancer / whole sample = ★**300 / 500 = 60%**
  - incidence at 10 y = new cases within the 10 y / whole sample = ★**200 / 500 = 40%**

Note on the arithmetic: strictly, the incidence denominator is the population *at risk* — the 400 who were cancer-free at baseline (200/400 = 50%). The lecture divides by the whole 500; reproduce its method if the stem mirrors this example.

7.3 Proving causality of a risk factor

1. **Dose response**: the higher the dose → the higher the chance
2. **Temporal relation**: did the exposure **precede** the condition, or follow it?
3. **Consistency**: findings are the same everywhere

§8 Analytical studies: cohort & case control

Table 8 — Cohort vs case control

	Cohort	Case control
Direction	**Prospective**	**Retrospective**
Starts from…	The cause <exposure>	The disease <condition>
To reach…	A particular disease <effect>	A particular cause
Prevalence	Yes	No
Incidence	Yes	No
Causality	Yes	No
Data analysis	Relative risk & attributed risk	Odds ratio
Main drawback	Expensive · time consuming · attrition	"Egg and chicken" dilemma

8.1 Cohort study

- **Logic**: I have a harmful agent (smoking) → I search for its effect (periodontitis)
- **Method**: collect two or more groups — smoking group and non-smoking control group → follow up → analyse

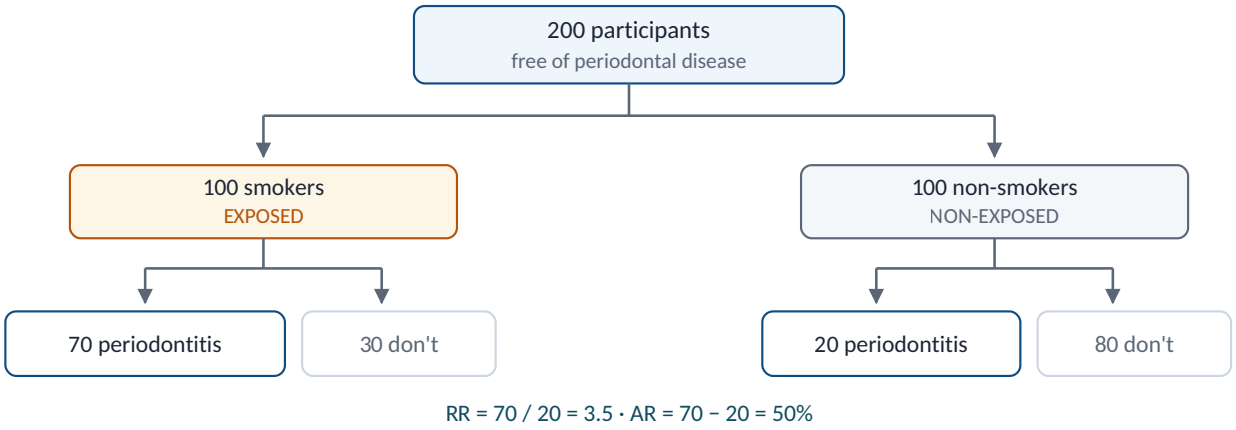

Diagram 1 — Cohort analysis: smoking → periodontitis. Both arms start disease-free; the split is by exposure, the outcome is counted at follow-up.

- **Relative risk (RR)**: diseased among exposed ÷ diseased among non-exposed
  - worked → ★**70 / 20 = 3.5**
  - RR > 1 → exposure is a **risk factor** · RR < 1 → exposure is **protective**
- **Attributed risk (AR)**: diseased among exposed − diseased among non-exposed
  - worked → ★**70 − 20 = 50%**
  - reading: smokers have a 70% chance of periodontitis — **50% because they smoke**, 20% from other risk factors (poor oral hygiene, diabetes mellitus)
  - i.e. smoking raises the chance of developing periodontitis by 50%

Wording note: the lecture calls the 70% and 20% "prevalence". Because a cohort follows disease-free people forward, these are strictly *incidence* (risk) — which is exactly why a cohort, and not a cross-sectional survey, can yield a relative risk.

8.2 Case-control study

- **Logic**: I have a disease (primary teeth discoloration) → I search for the causative agent (tetracycline during pregnancy)
- **Method**: two groups — cases with discoloured teeth and controls with normal teeth → take the history → analyse

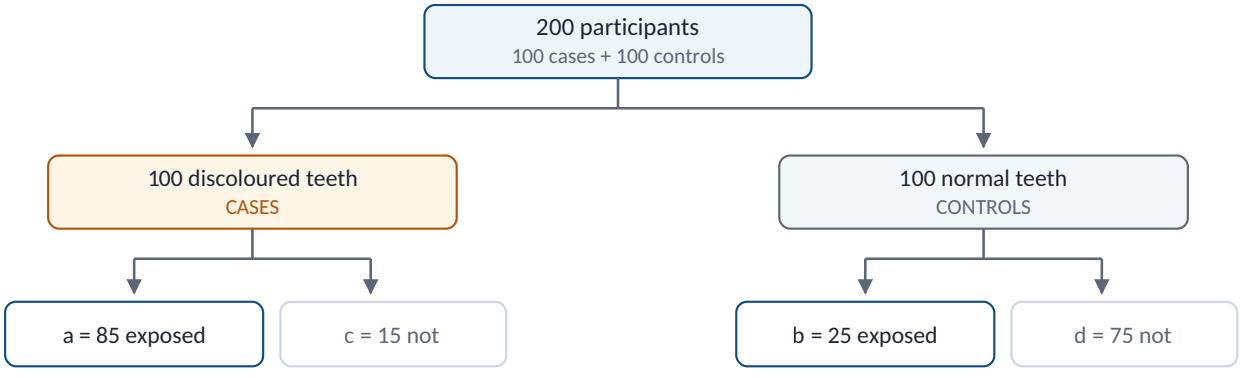

Diagram 2 — Case-control analysis: tetracycline in pregnancy → primary tooth discoloration. Groups are fixed by *outcome*; exposure is then recalled from the history.

Table 9 — The 2 × 2 table and the odds ratio

	Disease — CASES	No disease — CONTROLS
Exposed	a	b
Unexposed	c	d

- **Odds of exposure in cases**: cases with exposure ÷ cases without = **a / c**
- **Odds of exposure in controls**: controls with exposure ÷ controls without = **b / d**
- **Odds ratio**: (a/c) ÷ (b/d) = ★**ad / bc**
  - OR > 1 → risk factor · OR < 1 → protective factor
  - tetracycline example → (85 × 75)/(25 × 15) = **17** → strong risk factor [worked from the lecture's numbers]

★ EXAM PEARL

Design follows the question: **exposure known, outcome unknown → cohort** (RR, AR, incidence, causality); **outcome known, exposure unknown → case control** (OR only). If a stem gives you an odds ratio, the study was retrospective.

§9 Bias, and practising evidence-based dentistry

9.1 Bias

- **Definition**: selectively choosing the evidence to support one's own view
- **Forms named in the lecture**:
  - **selective bias** · **publication bias** — positive studies preferentially published
  - **seduction of authority** — accepting a claim because of who said it
  - **false idol of technology** — newer assumed better
  - **financial considerations** · **"let sleeping dogmas lie"** — unexamined habit

9.2 What evidence-based dentistry is

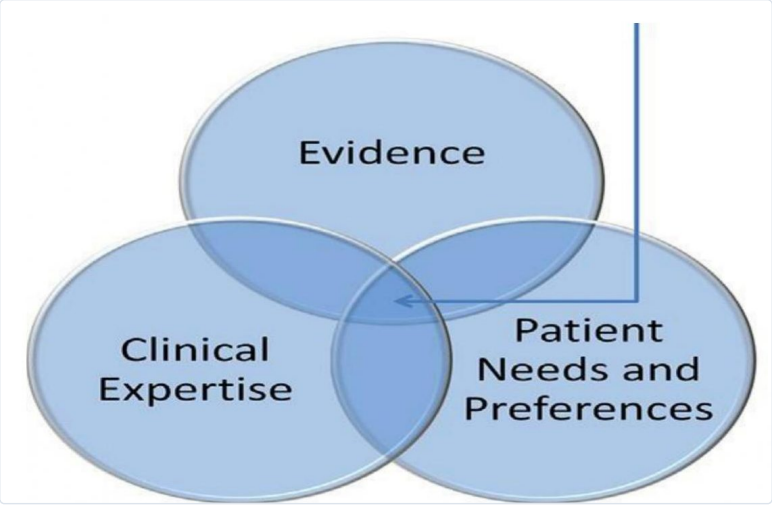

Fig. 3 — Evidence-based dentistry sits where all three overlap → **shared decision-making**.

- **Any approach to oral health care requires integration of three things**: ★**relevant evidence · clinical skills · patient needs and preferences**
  - the overlap of all three = shared decision-making

9.3 The five steps

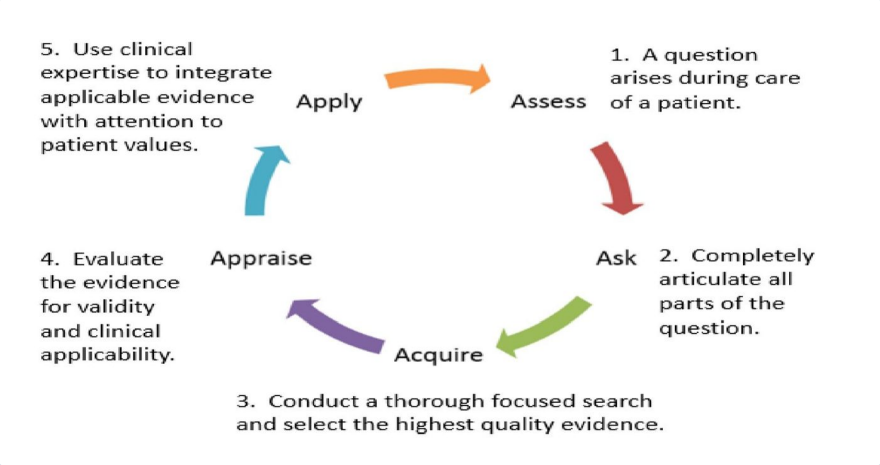

Fig. 4 — Assess → Ask → Acquire → Appraise → Apply, then back to Assess.

1. **Assess**: a question arises during care of a patient
2. **Ask**: completely articulate all parts of the question → PICO
3. **Acquire**: conduct a thorough focused search and select the highest-quality evidence

4. **Appraise**: evaluate the evidence for **validity and clinical applicability** (validity + reliability)
5. **Apply**: use clinical expertise to integrate the applicable evidence with attention to patient values — *if you are skilful enough to do it and the patient approves* → then **assess the outcome**

9.4 Step 1 in detail — PICO

- **P** — population or problem: age · smokers · pregnant … etc.
- **I** — intervention
- **C** — comparison
- **O** — outcome

- **Example 1**: for a patient with an osseointegrated implant **who smokes** (P) compared to a **non-smoker** (C), what is the **proportion of implant loss at 10 years** (O)?
- **Example 2**: in a patient with a recurrent operculum covering the lower left third molar (P), will **extraction** (I) compared to **operculectomy** (C) reduce the **recurrence rate** (O)?

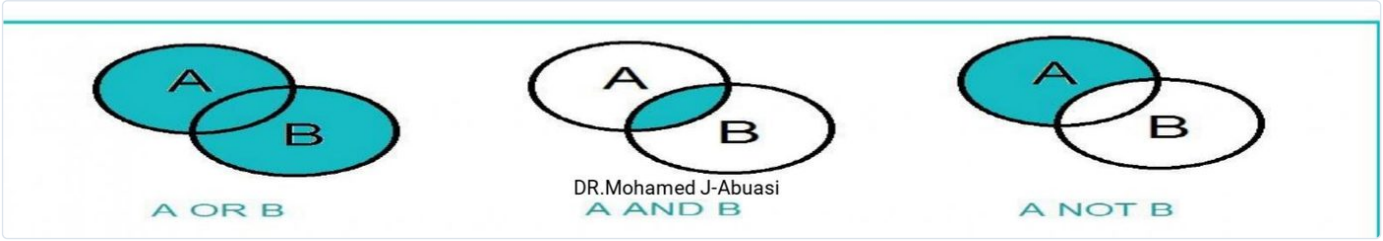

Fig. 5 — Boolean operators: **OR** widens (either set), **AND** narrows (overlap only), **NOT** excludes. Also: alone, together vs … etc.

9.5 Step 2 in detail — matching question to design

- **Question about drugs or techniques** → ★**RCT**
- **Question about aetiology** → ★**case control**
- **Question about long-term prognosis** → ★**cohort**

> **KEY POINTS**
> E-databases: **Medline** → **PubMed** · **Cochrane Library** → **systematic reviews** · evidence-based journals.

> **★ EXAM PEARL**
> Two-part discriminator examiners love: the **question type picks the design** (therapy → RCT, aetiology → case control, prognosis → cohort), and the **design picks the statistic** (RCT → ARR/NNT/RR, cohort → RR/AR, case control → OR).