

The Real World: How Integrated data can be used to improve patient care?

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Outline of the Presentation

- ▶ Importance of EBM
- ▶ Pitfalls of EBM
- ▶ Solution: Data-Based Medicine
- ▶ Advantages and Challenges of DBM
- ▶ Integration of DBM and EBM



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History of Decision-Making in Medicine



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Ancient medicine

- Religious and spiritual theories

Individual preference-based

- Highly subjective decision making

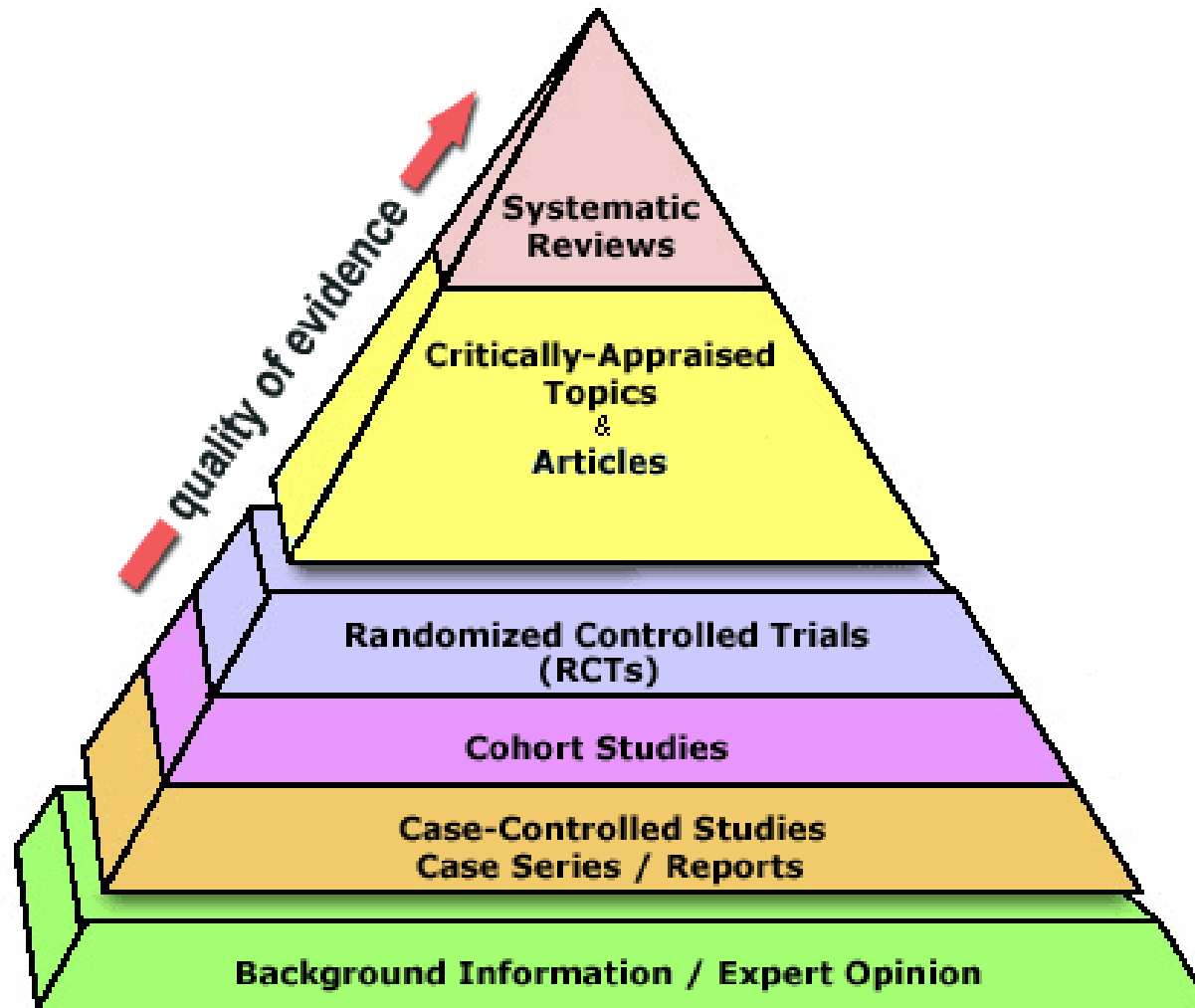
Experience-based medicine

- Based on individual or group observations

Evidence based medicine

- Followed the introduction of epidemiological methods

Quality of Evidence in EBM



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Randomized Clinical Trials: the Heart of EBM

- ▶ RCTs are defined as *scientific experiments where the people being studied are randomly allocated one or other of the different treatments under study*
- ▶ Considered the **gold standard for a clinical trial**
- ▶ Form the basis of:
 - ▶ Systematic reviews
 - ▶ Meta-analyses
 - ▶ Treatment guidelines



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Pitfalls of EBM

EBM hinges on RCTs: to the point of overreliance

- EBM ‘dogmatically refuses to acknowledge’ other valid sources of health data
- Results may not be relevant for all treatment situations¹

RCTs are expensive

- There will be always a higher *demand* for RCTs than *supply*
- Priorities are influenced by the interests of sponsors

Certain populations are usually excluded from RCTs

- Patients with comorbidities, extremes of ages, racial minorities etc
- Restricts generalizing²

Other Pitfalls

- Publication bias: not all studies are published
- Not all conditions have RCTs, especially rare conditions
- Lack of access to clinical trial data
- ‘Statistically significant’ benefits may be ‘marginal’ in actual clinical practice³

1. Upshur RE et al. J Eval Clin Pract 2001;7(2):91-6
2. Rogers WA. J Med Ethics 2004;30(2):141-5
3. Greenhalgh T et al. BMJ 2014;348:g3725



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EBM does not permit
generalization of data into
a 'Real-World setting'

*Its most prominent
pitfall*



Data-based Medicine

Data-based Medicine (DBM) is an emerging concept

- It depends on the analysis of the extensive health records that are available across a particular geographic data from all possible sources (often termed as 'Big data') for taking healthcare decisions.

Big data analysis can provide multiple forms of health-related information about any condition:

- Natural history of disease
- Effectiveness of any treatment modality
- Impact of an intervention on any objective parameter
- Cost-effectiveness of any treatment modality

Latest Entry: Data-Based Medicine



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Ancient medicine

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- Highly subjective decision making

Experience-based medicine

- Based on individual or group observations

Evidence based medicine

- Followed the introduction of epidemiological methods

Data based medicine

- Depends on the analysis of 'Big Data'

How is DBM Different from EBM?

DBM relies on Real World Data

- Outcomes of analyses will be relevant for most treatment situations in the real world: generalization is easy

Conflicts of interests are less

- Unlike RCTs, investment not needed for data collection

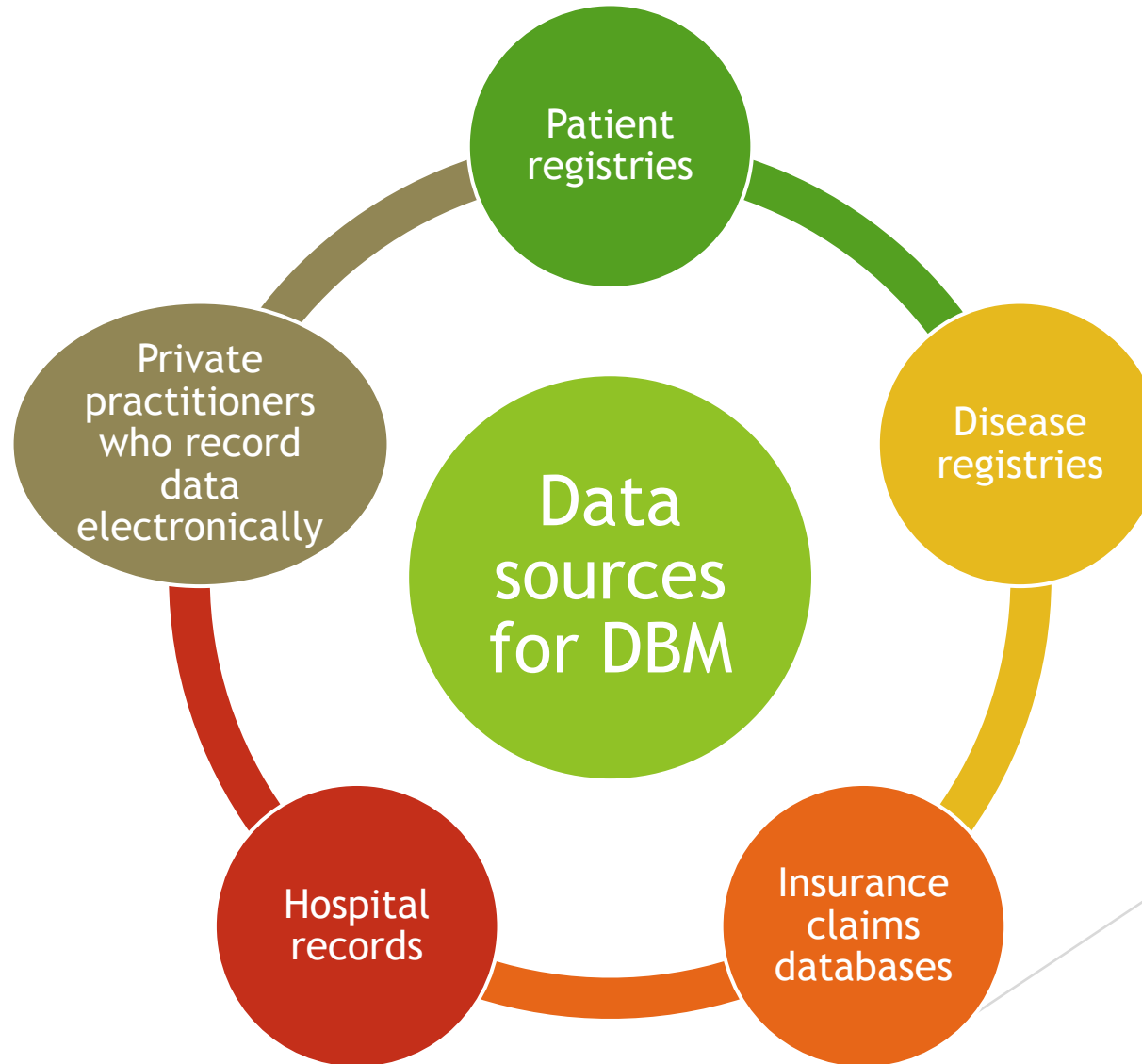
No question of excluded populations in DBM

- Health data of all patient sub groups are available

Others

- Minimal risk of publication bias
- Larger sample size → better generalization
- No question of lack of access to clinical data

Sources of Data for DBM



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Integration of EBM and DBM



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Real World Data

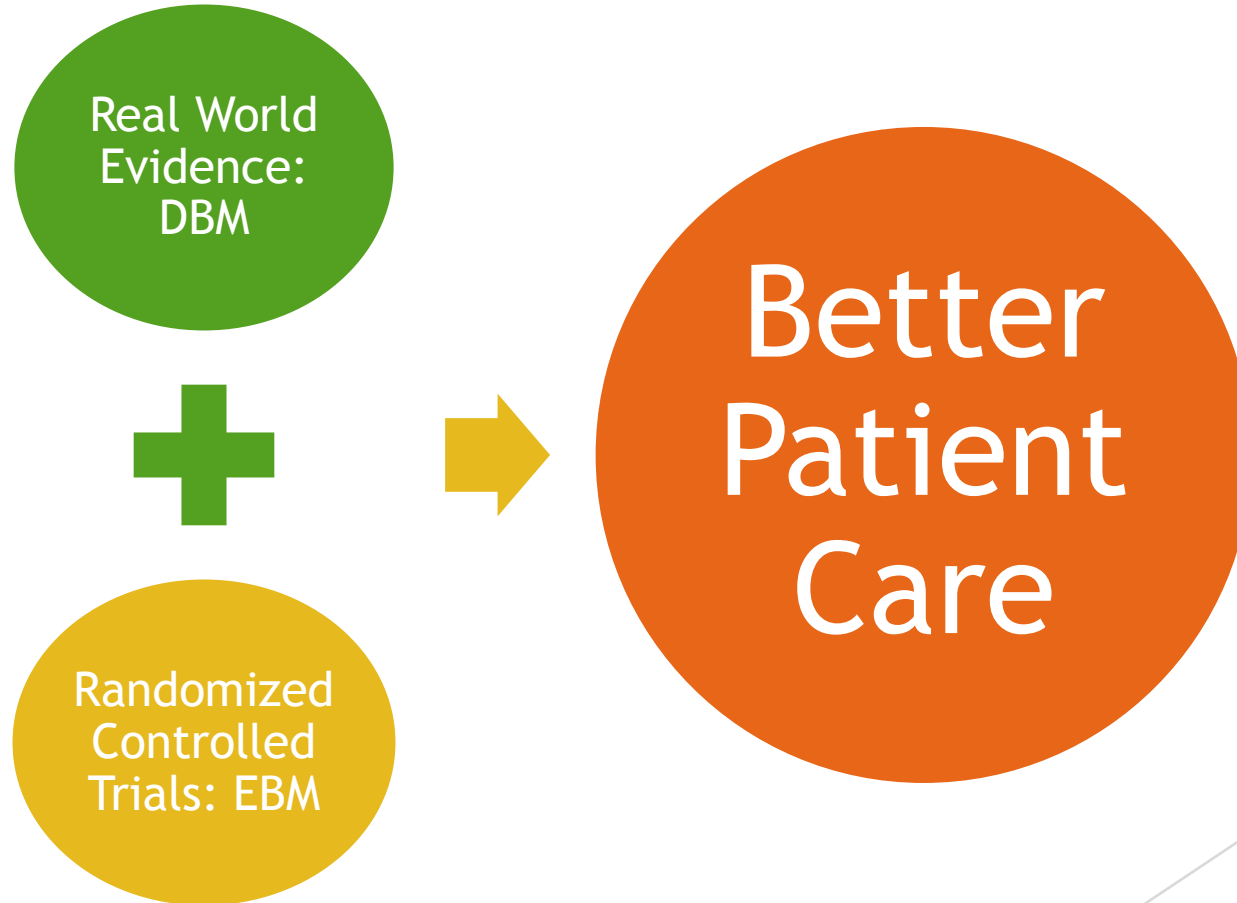
A retrospective glance
at what actually
happened

Randomized Controlled Trials

How a treatment will work in
an ideal situation

RWD and RCT Data
Complement One
Another

Integration of EBM and DBM Contd



DBM in India: Challenges

- ▶ First and foremost is the *availability of data* in a country like India:
 - ▶ Electronic recording is not very popular
 - ▶ Doctor-shopping is a widely prevalent practice among patients
 - ▶ Cross-systems practice
 - ▶ Poor penetration of health insurance → insurance claims data also not promising
 - ▶ Concepts of disease registry and patient registry not popular
- ▶ Management of the huge data requires significant experience and expertise
- ▶ Analysis of huge data requires expertise, and can be expensive
- ▶ Privacy and confidentiality issues

Conclusions

- ▶ Evidence-based Medicine (EBM), considered gold standard of clinical practice, depends heavily on randomized controlled trials (RCTs)
- ▶ RCTs have certain disadvantages which forbid proper generalization of results into the population
- ▶ Most of these disadvantages may be overcome by implementation of Data-based medicine (DBM), which depends on the analysis of Real World Data (RWD)
- ▶ RWD and RCT data provide complementary information
- ▶ Best outcomes can be obtained by integrating DBM and EBM



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References

1. Upshur RE et al. J Eval Clin Pract 2001;7(2):91-6
2. Rogers WA. J Med Ethics 2004;30(2):141-5
3. Greenhalgh T et al. BMJ 2014;348:g3725
4. Masic I et al. Acta inform med 2008;16(4):219-25
5. Croft P et al. Spine (Phila Pa 1976). 2011 Aug 1;36(17):E1121-5



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The background features abstract, overlapping green geometric shapes in various shades, primarily on the right side of the slide. The shapes include triangles and polygons, creating a modern, layered effect. The colors range from light lime green to dark forest green.

Thank You!

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