Data-Based Medicine v/s Evidence Based Medicine

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Evidence Based Medicine (EBM)
- The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients\(^1\)
- Initially defined in opposition to experience-based medicine
- Aims to improve clinical experience with better evidence\(^2\)
- An essential part of EBM is the use of clinical practice guidelines\(^3\)
- Regarded as the gold standard of clinical practice since 1990

History of Decision-Making in Medicine

Quality of Evidence in EBM

Randomized Clinical Trials (RCTs): The Heart of EBM
- Considered the gold standard for a clinical trial
- Scientific experiments where the people being studied are randomly allocated one or other of the different treatments under study
- Form the basis of:
  - Systematic reviews
  - Meta-analyses
  - Treatment guidelines

Randomized Trials: Phases and Flow

Pitfalls of EBM
- Since EBM hinges on RCTs, the results may not be relevant for all treatment situations\(^2\)
- RCTs are expensive: there will always be a higher demand for RCTs than supply
- Since RCTs are expensive, the priorities are influenced by the interests of sponsors
- Certain populations (patients with comorbidities, extremes of ages, racial minorities etc) are usually excluded from RCTs → restricts generalizing\(^4\)
- Publication bias: not all studies are published, especially those with negative results
- Not all conditions have RCTs, especially rare conditions
- Lack of access to clinical trial data
  - “Statistically significant” benefits may be “marginal” in actual clinical practice\(^5\)

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

DBM: Sources for Data
- Sources include:
  - Patient registries
  - Disease registries
  - Insurance claims databases
  - Hospital records, when electronically recorded, such as HMIS in Maharashtra Government Hospitals
  - Private practitioners who record data electronically
- A compilation of data from all these resources will provide a huge database from which virtually any condition may be analysed

Advantages of DBM over EBM
- Data is sourced from real-world settings and not from ‘ideal’ settings often seen in RCTs: analysis of such data permit better generalization
- Larger sample size leading to better generalizations
- Availability of data for those conditions on which quality EBM is lacking
- Free from other disadvantages of EBM such as:
  - Non-exclusion of any population subset
  - No problem of publication bias, since data is already recorded and available for analysis
  - No question of lack of access to clinical data

Challenges in Implementing DBM
- 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 big data

 Though DBM has its advantages, there are some challenges in its implementation, especially in a country like India
- If implemented properly, DBM has the potential to bring about a significant improvement in the way medicine is practised

References

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