EVIDENCE BASED PRACTICE

Kiron SS, Theertha.S, Krishna DS, Megha S

Author’s details:

1. Dr Kiron SS, MPharm, PhD

Professor,

Department of Pharmacy Practice,

College of Pharmaceutical Sciences,

Government Medical College, Kannur-670504, India

Email: [drkironss@gmail.com](mailto:drkironss@gmail.com)

1. Ms. Theertha S, Pharm D

Pharm D (Intern)

Department of Pharmacy Practice,

College of Pharmaceutical Sciences,

Government Medical College, Kannur-670504, India

Email: [theerthakannan2000@gmail.com](mailto:theerthakannan2000@gmail.com)

1. Ms. Krishna D S, Pharm D

Pharm D (Intern)

Department of Pharmacy Practice,

College of Pharmaceutical Sciences,

Government Medical College, Kannur-670504, India

Email: [krishnads466@gmail.com](mailto:krishnads466@gmail.com)

1. Ms. Megha S, Pharm D

Pharm D (Intern)

Department of Pharmacy Practice,

College of Pharmaceutical Sciences,

Government Medical College, Kannur-670504, India

Email: [meghasomanath24@gmail.com](mailto:meghasomanath24@gmail.com)

INTRODUCTION

The definition of Evidence-Based Medicine states that it integrates clinical knowledge, patient values, and the best available evidence when making decisions about a patient's medical care. Evidence based medicine (EBM) is the conscientious, explicit, judicious and reasonable use of modern, best evidence in making decisions about the care of individual patients. EBM integrates clinical experience and patient values with the best available research information. Care for one's own patients necessitates the need for clinically essential knowledge regarding diagnosis, prognosis, therapy, and other clinical and medical difficulties. Evidence-based medicine is an ongoing, self-directed learning process [1].

EBM recommends focusing on reading topics linked to particular patient problems rather than routinely scanning the contents of hundreds of journals for intriguing papers. To stay up to date with the literature, it may be more efficient to develop clinical queries before examining current databases. Evidence-based medicine "transfigure the academic practice of reading and evaluating literature into the practical practice of applying it to help specific patients, while simultaneously improving the physician’s knowledge [1]. With philosophical roots dating back to mid-1800s Paris and beyond, evidence-based medicine continues to be a hot topic for physicians, public health professionals, buyers, designers and the public. The main difference between evidence-based medicine and conventional medicine is not that EBM takes evidence into account, while the latter does not. Both consider the evidence; However, EBM requires better evidence than traditionally used. One of the greatest achievements of evidence-based medicine has been the development of systematic reviews and meta-analyses, methods by which researchers identify studies on wide range of topics, separating the best of them, and then critically analyse them to summarize the best available evidence [2]. The future holds promise for improved primary research, better EBM summaries, better access to those summaries, and better practice-based implementation systems. Computerized decision support tools for clinicians make it easy to combine individual patient data with the best available research data [3].

Flowchart of Evidence Based Practice (Figure1)

The practice of EBM involves five essential steps; which includes converting information needs into answerable questions. To seek out the best evidence to be able to answer those questions, the evidence is assessed critically for its probativeness and usefulness and the results of the examination are applied to clinical practice.Converting a clinical problem into an answered question could be one of the trickiest parts of using EBM [6] Many questions may come up when we encounter a patient with a specific issue, and we would like answers. These inquiries are typically complicated and poorly organised, and they may not even be clear to us. A well-crafted clinical query should be the first step in the EBM process. As a result, we should practice turning our informational wants into questions that can be answered [4]. Generally, a good question should be relevant and specific, distinctly communicated, clear in the objective and necessity of inquiry, one that will reduce the time required to obtain the answer [5]. A good clinical question should have four (or sometimes three) essential components: the patient or problem in question; the intervention, test, or exposure of interest; comparison interventions (if relevant); the outcome, or outcomes, of interest [4].

Considering these points, it is recommended to assign as many clinical questions for EBM as much as possible by applying the standard of PICO criteria, where 'P' denotes 'population' or 'patients', 'I' 'intervention' or 'exposure', 'C' 'comparison', and 'O' 'outcome'. After creating a clinical questionnaire, it is important to confirm its category in order to understand the kind of data the question will need. Diagnosis, prognosis, therapy, and risk (factors) are frequent categories of inquiries, and the category determines the type of study required to provide an answer. A cross-sectional study or a case-control study is the best research strategy to address a clinical topic if it falls under the diagnosis category. Cohort studies are useful for clinical questions in the field of prognosis. A randomized controlled study or a thorough literature analysis of randomized controlled studies is required if the category is therapy. A case-control study, cohort study, or randomized controlled trial is required if a clinical topic falls under the category of risk (factors) [5].

Patient Population: The ultimate goal of EBM is to inform clinical decisions about each patient. Therefore, it is ideal to seek answers from studies that included subjects very similar to the patients. If the target group is defined too broadly, the study results may not be applicable to patients whose characteristics differ from the typical subjects. However, there is also a risk if the target group is defined too narrowly. High quality studies in well-defined patient’s groups are often not available, and alternatives subgroup analysis of larger, more comprehensive studies can be problematic due to serious methodological issues. Intervention: In formulating PICO question, it is important to define the metric under consideration. A similar approach is used to assess questions related to diagnosis or prognosis. Comparison: In randomized treatment trials the comparison group can be placebo, conventional treatment or active treatment. Placebo-controlled studies have two clear advantages: they facilitate binding and control of the placebo effect (non-specific treatment effect). However, they cannot be used to compare the effects of real choices. It is important that the comparison intervention is clinically appropriate (ie, an alternative intervention that could realistically be considered) [6].

Outcomes: It is important to consider all patients important outcomes (including benefits and harms). It is not enough to think about benefit or harm in general; you must be specific about the results of interest. In particular, outcomes must be well defined, measurable, reliable, sensitive to change and truly assess clinically important aspects of patient’s health. Specific questions related to the types of outcomes measured in clinical trials include: Composite endpoints- Using a combination of multiple composite endpoints has the advantage of increasing the statistical power of a study, but can be difficult to interpret. Interpretation is easy if all component outcomes are equally important to the patient and the intervention affects them all in the same way. However, this is rarely happening. When the effects of an intervention are not consistent across outcomes and outcomes are assessed differently, interpretation of the combination is difficult. Therefore, studies of a composite endpoints for the primary outcome should also report the results of each individual outcome that makes up the composite outcome. For example, in a study comparing coronary artery bypass grafting with percutaneous angioplasty and stenting in severe coronary artery disease, the primary outcomes were death, severe coronary disease with a primary outcome of death, stroke, myocardial infraction or need for repeated revascularization compared with bypass surgery, percutaneous intervention has a significantly lower risk of stroke, but a significantly higher risk of repeat revascularization. In case, focusing on the aggregated endpoint will not help. Soft outcomes- Many clinical trials focus on objective outcomes that includes the hard outcomes of death and disease (myocardial infarction, stroke and limb loss). Softer outcomes that measure function, pain and quality of life are less common but are the primary outcomes of interest in many questions. Difficult results are usually easy to measure without special instruments [6]

Table (1) Shows an example of PICO-SD specified for a question established by the Propofol Task Force Team of the Korean Society of Anesthesiologists according to the "Clinical Guidelines of Propofol Sedation for Non-Anesthesiologists." The clinical question is, "Can combination therapy with propofol and another sedative make the risk of adverse effects lower than that of propofol monotherapy in patients undergoing sedation therapy?" [5]

|  |  |  |
| --- | --- | --- |
| PICO | Description | Example |
| P: Patients or populations | Information on what subjects’ group do I need | Patients undergoing sedation therapy |
| I: Intervention or exposure | Results of which interventions or exposure do I need | Combination therapy within propofol and others sedative |
| C: Comparison or control | What is the alternative to compare where an intervention is not performed or another intervention Method is applied | Propofol mono therapy |
| O: Outcome | What is effect or result of the intervention | Risk of adverse effects |

PICO-SD example (Table 1)

EVIDENCE SOURCE

Despite the ease with which medical information is currently available, quick research skills are still essential. Depending on the purpose of the information search, several methodologies are applied. A key component of EBM is the ability to quickly and accurately respond to a specific clinical query. To master this method, most physicians do not require complex technical knowledge. It would be challenging and simply impossible for an individual physician to address all crucial clinical questions by reading, evaluating, and summarizing the evidence. Entrusting the task to reliable sources is vital [6]. Many sources are available online for this purpose, through an online survey an attempt was made to determine the frequency of usage of Wikipedia among medical students. Students often engage with them instead of more established authoritative resources since they have simple user interfaces [7].

Traditional patient care practitioners use data from all the four phases of the healthcare research process. Those who employ the concepts of EBP, however rely on information collected during the clinical research stage, to guide their clinical judgement. Development of EBP is crucial because practitioners who utilize EBP use information from the literature base than just clinical experience and pathophysiology. The reports of primary research trials and investigations as well as secondary reports that synthesize, analyse and present data from numerous research studies are both included. Systematic review articles, meta-analysis, economic assessments and clinical practice recommendations are few examples of secondary reports [8].

A choice is made between a database, which comprises of articles and references; these include Cochrane library, MEDLINE, EMBASE. A navigation portal with a build in search engine such as PubMed are included [6]. In MEDLINE, search techniques can find legitimate studies with a significant level of specificity and sensitivity. Combing MeSH terms and text words while trying to find articles that match methodological criteria enhances the sensitivity of methodological search terms in MEDLINE [9]. The Cochrane Library, which was created by the Cochrane Collaboration, is a more reliable source of data on clinical research. The collaboration is a global volunteer organization and network of medical professionals, patients and the members of the general public who are committed to gathering references to reports of clinical research for therapy studies, developing broadened abstracts for meta-analysis and systematic reviews, and there authoring and periodic updating [8].

Characteristics of reliable data for clinical research includes; readily accessible data for therapeutic decision making. Data should be directed to particular clinical question. Portal and focused on the most recent information [6]. Multiple databases may be accessible through a single access gateway. Access portals might also offer tools to coordinate citations and creating citation maps. Citation maps are database of citation acquaintances between different data. These might be either incoming including more recent reports citing the index piece, outgoing including publications cited in a certain paper’s bibliography. Analysing citation maps is an ethical way of literature search, yielding unforeseen and beneficial discoveries [6].

The COSI (Core, Standard, Ideal) model, which is provided by the US NLM, serves as the framework for the literature review. The phase Core refers to the essential components of a literature review, or the bare- borne database needed in a matter of minutes to identify the best outcome. A manual search of core journals as well as searches of databases that are not “core” are included in the term “Standard”. It refers to the customary scope of the literature review. Ongoing trials, unpublished research data, grey literature make up the “Ideal” portion [10]

COSI MODEL (Figure2)

Pre-defined search phrases created for a particular purpose are called search filters. These are specific to both database and portals. The filters are platform specific which meant that for seemingly equivalent searches, the results could be substantially distinct [6]. In order to understand hierarchies of evidence, we have set out, in order to discover the best evidence, you need to be able to detect high level of information and the virtues of starting a data search with more extensive processing [11].

EVIDENCE BASED RESOURCES

Resources (Figure 3)

Original Research (Primary): Data from individual or groups of subjects with well-defined physicians and geography or other variables are collected for primary research. EBM practitioners should take the hierarchy of evidence into account when performing primary research to reduce the possibility of bias. Well conducted randomized clinical trials outperform observational studies, which exceed unsystematic clinical observations for studying assessing therapy or harm. The research question will determine the most effective study design. Most effective method being Randomized Control Trial for determining the benefits and risks of an intervention. Prospective cohort are effective method for determining the risk factors for disease and prognosis [6].

Systematic Review and Meta analysis: The most effective evaluation is those that follow a systematic process. Compared to typical reviews, they are more scientifically organized and translucent. To eliminate publication bias, reviews take special attention to include all compelling data [12]. The most sophisticated types of documents are summaries and guidelines. Guidelines should ideally be a synthesis of original research, clinical experience, systematic reviews and patient preferences. The greatest summaries and recommendations are a thorough synthesis of the best available data. The quality of the published guidelines varies greatly. There are several instances of guidelines on the same subject providing contradicting advice [6,13].

Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system offers guidelines for ranking evidence quality and grading recommendation strength in the sector of health care [14]. Strong and weak recommendations can be distinguished by GRADE. Strong recommendations eliminate the need for a thorough evaluation of the evidence with each patient since they symbolize a clear preference for one alternative and should be applicable to virtually all patients. When there is a secure balance between the desired and undesirable effects of alternative management strategies, uncertainty about the effects variables, preferences and cost effectiveness, here weak recommendations are appropriate [13].

VALIDITY OF THE EVIDENCE

Clinicians need to be capable of analyzing research publications that are crucial to their field. Skills in thoughtful assessment help physicians gain autonomy and expertise. Critical thinking abilities can also aid physicians in making more informed decisions on the sources of information they implement, opting for those that provide clear guidelines for evaluating the strength of the evidence. Through the facilitation of focused attention on exceptional articles and omission of weak ones, these abilities can also increase the effectiveness of casual reading [6].

There are a variety of suggestions that outline requirements for carrying outline reporting various types of studies. According to the type of study, the set of criteria endorsed by the International Committee of Medical Journal Editors (ICMJE) can help with the evaluation of specific studies critically [6]. The PRISMA Statement was developed to help authors publish systematic reviews and meta-analyses more effectively. PRISMA can be used as a foundation for publishing systematic reviews of various kinds of research, notably evaluations of therapies, it has been mostly applied to randomized trials. PRISMA may also be beneficial for evaluation [15].

To enhance the reporting of randomized controlled trials, the Consolidated Standards of Reporting Trials (CONSORT) Statement is applied globally [16]. The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) suggestions can be widely used to help with protocol design, materials, and implementation, trial registration, appraisal and potency and ultimately, transparency for patient care [17]. The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) initiative, which aims to improve the reporting of observational studies in epidemiology, has produced guidelines on what information should be included in an observational study’s accurate and comprehensive report [18]. The STARD (Standards for Reporting of Diagnostic Accuracy) initiative’s goal is to raise the standard of diagnostic study reporting. Authors may utilize the items on the checklist and the flowchart to describe key aspects of the study’s design and conduct, test execution and outcomes [19]. The TRIPOD (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis) Statement intends to enhance the reporting of research creating, validating, or updating a prediction model, whether it is used for prognostic or diagnostic reasons. Regardless of the research techniques employed, the TRIPOD statement strives to increase the transparency of publishing a prediction model study [20].

Evaluating both Internal and External validity is the main goal of critical evaluation (Figure 4)

Internal Validity: An analysis of a study’s internal validity determines if the methods used in its determines if the methods used in its planning, execution and analysis provide reliable responses to the research objectives. Internal validity isn’t a number that can be calculated; it is a subjective concept. The presence of systematic error is investigated by looking at internal validity. Such systematic inaccuracy may be caused by selection bias, performance bias, detection bias or attrition bias [21].

BIAS: Any systematic mistake that can give a false impression of the genuine effect is considered biased. With the intention of decreasing prejudice, randomized trials are done and well conducted studies typically have a minimal risk of bias. Clinical trial conduct errors, however have the potential to skew the outcomes. Chance, which is a random error that exists in every observation. By examining a large number of patients, the possibility of chance providing inaccurate results can be reduced. P-value are sometimes misconstrued as the like hood that the results are the result of chance. Instead, p-values indicate the likelihood that the study would uncover a difference if the null hypothesis were true [6].

External Validity: Examining a study’s external validity reveals its finding may be applied to different context. Studies are based on samples and if the sampling was random and representative of the population, findings can be correctly generalization of the study’s findings to that group. However, results might not apply to different groups. Therefore, research that limit concurrent treatment and exclude very ill and suicidal individuals, patients with personality disorders, substance abuse and other medical comorbidities, have a poor external validity. Low levels of external validity are also present in short term studies of patients who require months to years of treatment. Both internal and external validity are based on judgment [21].

Indirect Evidence: practitioners may be predisposed to dismiss the evidence when a study includes a group that is somewhat different from the one that the EBM practitioner is interested in. in fact, when there is lack of direct data, this kind of indirect evidence can aid in informing medical decisions. However, there is typically less confidence in the projected conclusions than there would be if there were clear evidence. Subgroup Analyses: One tactic is to use subgroup analyses, which compare results based on various patient characteristics, when the study does not focus on the particular patient population of interest. To prevent making erroneous inferences, care should be used while evaluating the results of subgroup analysis. Potential issues comprise of: Reporting Bias, Multiple comparisons, Lower statistical power [6].

EBM practitioners should ask the following questions to reduce the possibility of obtaining inaccurate inferences from subgroup analysis:

1. Can the apparent subgroup effect be explained by chance?
2. Is the effect consistent across studies?
3. Was the subgroup hypothesis one of a few developed beforehand with a clear direction?
4. Is there strong evidence preexisting biological support?
5. Is the evidence for the effect based on within or between study comparisons?
6. Did the subgroup analysis have a plan before the information was gathered?
7. How did each subgroup fare?
8. Is the distinction between the groupings statistically tested? [22,23].

In particular, failing to specify subgroup analyses a priori and failing to test for effect modification, subgroup differences reported in randomized controlled trials frequently have shortcomings, few are corroborated in subsequent meta-analysis or randomized controlled trials [24].

APPLYING EVIDENCE

We must determine if a piece of evidence may be applied to a specific patient or demographic once we have determined following critical appraisal that it is legitimate and significant. We must consider the patient's own values and circumstances when making this choice. To enable the patient or parents, or both, to make an informed choice, the evidence addressing both efficacy and hazards should be thoroughly reviewed. This method enables the development of a "therapeutic alliance" with the patient and the parents and is in line with the core tenet of EBM: the integration of solid evidence with clinical know-how and patient values [4].

Patients differ in terms of their values, interests, expectations, and circumstances because no two people are the same. Patients are frequently found in circumstances that are distinct from those that have been searched for and assessed. As a result, it might not be suitable to treat patients using the ideal evidence that was gathered and examined. Decisions in this situation should take into account the patient's situation as well as the accumulated evidence. Additionally, doctors with various levels of training, experience, and specialization may favour various therapy modalities. As a result, the retrieved data can be at odds with the preferred treatment strategy chosen by each practitioner. In such situations, conflicts could arise. In these situations, EBM might aid the patient in selecting an intervention or course of treatment [5].

The “know-do gap” is a discrepancy between the best available evidence’s recommendations and actual practice occurs at regular intervals. There are many sources for the gap, including confusion about how results from large studies apply to specific patients, ignorance or distortion of the evidence, and inability to structure treatment in a way that advocates the use of evidence [25]. Lack of knowledge is the cause of inability to act in accordance with the best available evidence. But information by itself rarely modifies conduct [6]. Variations in initial risk- as indicated, ambiguity about whether the findings of large studies apply to a particular patient may restrict the use of evidence in practice. The response of patients in clinical trials often does not follow a predictable pattern; rather the outcome of treatment varies from patient to patient. Treatment effect heterogeneity is synonym for this. In general, only meta-analysis of numerous trials or single trials that prospectively evaluate for distinctions in treatment effect across designated subgroups examine treatment effect heterogeneity [26]. Asymmetric distributions of treatment or side effects are also possible based on baseline risk, though less so than for treatment advantages. Regardless of baseline risk, all patients generally experience the same costs and hassles of treatment. Patients with low baseline risk for important outcomes can therefore have more negative side effects than positive side effect from treatments [27].

Advantages and Disadvantages of EBM (Table 2)

|  |  |
| --- | --- |
| ADVANTAGES | DISADVANTAGES |
| Clinicians update knowledge base routinely | Time consuming |
| Improved understanding of research methods | Informed overload |
| Physician becomes more critical in use of data | Time needed for team conferencing, planning and review |
| Increased confidence in management decisions | Requires financial sources to establish resource infrastructure- library, office, computers etc |
| Better reading habits | May increase cost of care due to internet cost, subscription costs- online and paper resources |
| Provides framework for group problem solving, team generated practice | Requires programs, software information, CD-ROMS |
| Transforms weakness or paucity of knowledge in positive change | Exposes gaps in the evidence, may expose current practice as obsolete or dangerous |
| Can be learned by non-clinicians and other health care workers | Requires computer skills (but can be done with minimal computer literacy and skill) |

EVALUATION

After applying the evidence, the data, intervention and the EBM process are evaluated. The evaluation takes into account the importance of the quantity and quality of available evidence, the difficulty of obtaining evidence and results, the cost of the application, the rate of patient response and compliance and the difficulty of treatment. Application, clinical outcomes, impact of actual application and experienced changes in physician thinking and skills. There should be a feedback mechanism for the knowledge gained during the actual implementation process of the evidence so that others can perform the process well and the EBM implementation strategy can be improved. Additionally, doctors with various levels of training, experience, and specialization may favor various therapy modalities. As a result, the retrieved data can be at odds with the preferred treatment strategy chosen by each practitioner. In such situations, conflicts could arise. In these situations, EBM might aid the patient in selecting an intervention or course of treatment [28]. In order to determine whether an evidence-based practice has improved it is necessary to determine why some patient’s responses were different from those anticipated and make any necessary changes [29].

Current application of EBM:

* EBM is currently widely used by lawmakers, policymakers, and payers in the United States in a number of different contexts.
* EBM frequently plays a significant role in performance bonuses that pay doctors for meeting preset goals.
* The design of Health plan benefit is another area where EBM is becoming more significant. Health plans, both public and private, use evidence-based guidelines to determine which clinical procedures, treatments, medical devices and drugs are covered.

* The creation of continuing medical education (CME) content benefits from the use of EBM [30]

The steps that are required to be taken from the creation of evidence to its implementation (Figure 5)

CONCLUSION

EBM is a set of principles, tools and methods designed to ensure that medical decisions, guidelines and practices are, to the greatest extent possible, based on and consistent with good evidence of effectiveness and serve better patient care. Limitations of EBM includes; Lack of evidence (shortage of studies). Difficulty in applying evidence to care of a particular patient. Barriers to the practice of high-quality medicine. Lack of time to learn and practice EBM (Promotes lifelong learning through better focus). Lack of physician resources for instant access to evidence (EBM has worldwide applicability). Language barriers and lack of skills. Physician attitude can be the greatest limitation. Interpreting and understanding evidence syntheses, systematic reviews, and other analytical literature is a complex task. It is important that pain physicians understand the goals, principles, and processes of EBM in order to improve its applications. This information provides greater insight into the analytical reviews of interventional pain management presented here, but ultimately allows future data to be carefully selected, evaluated, and used in technically competent, ethically sound medical practice.

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Knowledge

Experience

Skills

Evidence available

Patient values and preferences

Clinical decision

Flowchart of Evidence Based Practice (Figure1)

COSI MODEL

Ongoing Trials,

Unpublished Literature,

Government Data,

Grey Literature

Expert opinion,

General database

Database with specialized content

**COre**

**Ideal**

PubMed, Embase, Cochrane Library

COSI MODEL (Figure2)

EVIDENCE BASED RESOURCES

Hierarchy of evidence

Original Research





EBM Resources

Nonpreappraised Research

Preappraised Research

Summaries

Processing Level

Original Studies

Meta analysis

Guidelines Decision Analysis

Resources (Figure 3)

VALIDITY OF THE EVIDENCE

Internal Validity

All patients who meet the inclusion criteria

Selection bias



Measurement and confounding bias

CONCLUSION

External Validity

(Generalizability)

Sampling

Evaluating both Internal and External validity is the main goal of critical evaluation (Figure 4)

EVALUATION

Integrate the evidence

Creating clinical policies from evidence

Policies applied

Research based evidence generation

The steps that are required to be taken from the creation of evidence to its implementation (Figure 5)