

Unit 2: Concepts in QUM: Evidence Based Medicine, Essential Drugs and Rational Drug Use

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2.1 The concepts of this unit, seen together

Unit 2 names the three concepts on which quality use stands. Evidence based medicine decides how a choice is justified: by the best available evidence, critically read. The essential medicines concept decides how a health system chooses its working set: a limited list, selected on need, efficacy, safety and value, kept supplied. Rational drug use decides how the individual prescription behaves: the right medicine, for the right patient, at the right cost to patient and community. The three operate at three levels, knowledge, system and prescription, and the pharmacist works at all three in a single day.

2.2 Evidence based medicine: definition

Evidence based medicine, shortened to EBM, is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients, integrating that evidence with individual clinical expertise and with the patient's values and preferences. Every phrase in the standard definition carries weight. Conscientious and judicious exclude both careless copying and rigid obedience: evidence informs the decision, it does not replace it. Current best evidence means the most trustworthy research available now, appraised for quality, not the most recent headline or the most convenient study. Integration means the three elements meet in one decision: what the research shows, what the clinician's experience judges about this patient, and what this patient, informed, actually wants. A choice made from evidence alone, ignoring a patient's circumstances, is not evidence based practice; neither is a choice made from habit alone while calling it experience.

2.3 The concept of evidence based medicine: why it arose and what it corrects

EBM arose because unaided clinical experience, however sincere, is systematically misled: memorable cases outweigh typical ones, treatments appear to work because disease naturally fluctuates and because patients and doctors both expect benefit, and new information reaches practice unevenly and late. The concept answers with a discipline: questions are stated precisely, evidence is searched for rather than remembered, studies are appraised for bias and for whether their results matter and apply, and practice is audited against what the evidence supports. Around the individual decision sits an evidence ecosystem the pharmacist uses daily: systematic reviews that gather and appraise all the studies of a question, evidence based guidelines that translate syntheses into recommendations for defined situations, and primary studies of the kinds the next section ranks. EBM is therefore a habit of justification. When a prescriber or pharmacist is asked why this medicine, the evidence based answer cites the evidence, its strength and its fit to the patient, and says honestly where evidence runs out and judgement begins.

2.4 The hierarchy of evidence, taught qualitatively

Evidence is ranked because study designs differ in how well they protect a result from bias, and the syllabus expects the ranking understood qualitatively, as a ladder of trust for questions about whether a treatment works. At the top stand systematic reviews and meta analyses of well conducted trials, because they gather the whole evidence on a question and appraise it together. Below them stand individual randomised controlled trials, in which allocation by chance balances known and unknown differences

between groups. Below trials stand observational designs, cohort and case control studies, which observe treatment as it occurs in practice and must argue their way around confounding. Below them stand case series and case reports, uncontrolled observations that can signal a question and, for rare harms, may be the first and only warning. At the base stand mechanism based reasoning and expert opinion, necessary, ubiquitous and the most easily misled. Two cautions complete the lesson. The ladder ranks designs for therapy questions; for questions of harm, prognosis or patient experience, other designs may be the best available. And a well conducted study of a lower design can deserve more trust than a badly conducted study of a higher one: the hierarchy guides appraisal, it does not replace it.

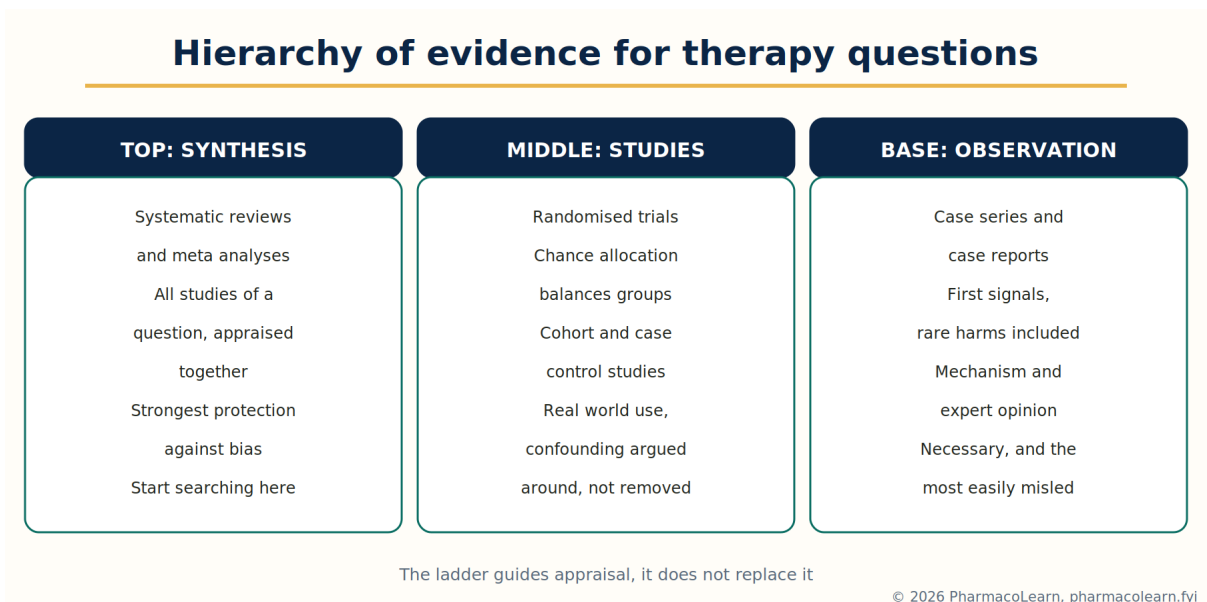


Figure: The evidence pyramid. Higher designs protect a therapy answer better against bias; appraisal still decides what any single study deserves.

2.5 Approach to evidence based medicine: the five steps

The approach to EBM is taught as five steps, and they should be learned as one continuous movement. Step one, ask: convert the clinical need into an answerable question, naming the patient or problem, the intervention, the comparison where there is one, and the outcome that matters. Step two, acquire: search efficiently for the best evidence that answers it, beginning where synthesis already exists, in guidelines and systematic reviews, before descending to primary studies. Step three, appraise: judge the evidence for validity, for the size and precision of its effect, and for its applicability to the patient in front of you. Step four, apply: integrate the appraised evidence with clinical expertise and the patient's values and make and explain the decision. Step five, assess: audit the outcome and the process, and let what happened refine the next question. In busy practice the steps compress: a pharmacist answering a ward question may run all five in minutes, using a guideline found quickly and appraised on known criteria. The compression is legitimate precisely because the steps are known well enough not to be skipped silently.

The five steps of evidence based practice

Ask: state the answerable clinical question



Acquire: search for the best available evidence



Appraise: validity, size of effect, applicability

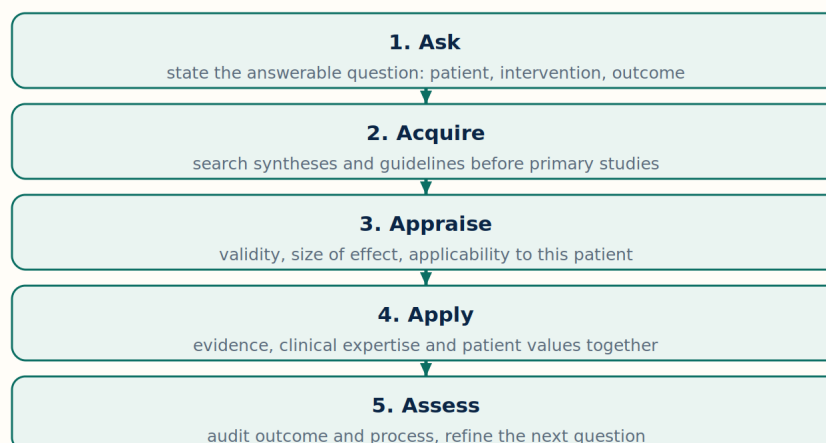


Apply: evidence, expertise and patient values together



Assess: audit the outcome and refine the next question

The five steps of evidence based medicine



Compression in busy practice is legitimate only when no step is skipped silently

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Figure: Ask, acquire, appraise, apply, assess. The fifth step is what turns one good decision into a better service.

2.6 Practice of evidence based medicine in clinical settings

In clinical settings EBM is practised through instruments, not only through individual searching. Clinical guidelines and local protocols carry appraised evidence to the point of decision and are the everyday form in which most evidence reaches most prescriptions; the professional skill is to use them knowingly, understanding what population and outcome they were built from and where the individual patient departs from them. Formularies restrict the working choice to medicines a committee has judged on evidence and value, which is EBM applied at system level before the prescription is written. Drug information services and medicines information pharmacists appraise evidence for questions too specific or too urgent for a guideline. Ward rounds, case presentations and journal clubs keep the appraisal habit social and current. The barriers deserve examination honesty: time pressure, information overload, guidelines that conflict, evidence that does not cover the elderly, the pregnant or the multiply ill patients who fill real wards, and commercial information that arrives faster and glossier than independent information. Naming a barrier and its countermeasure, protected appraisal time, independent sources, explicit documentation where practice departs from a guideline and why, is the mature answer.

2.7 Essential drugs: definition and need

Essential drugs, in current usage essential medicines, are those medicines that satisfy the priority healthcare needs of the population. The World Health Organization concept, in its standard form, selects them with due regard to disease prevalence and public health relevance, to evidence of efficacy and safety,

and to comparative cost effectiveness, and intends them to be available at all times, in adequate amounts, in appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The need for the concept is scarcity honestly faced. No system can stock, finance, quality assure and teach the safe use of every marketed product, and an unselected flood of products, many duplicating each other, dilutes all four: procurement budgets, quality control, prescriber knowledge and patient understanding. A limited, carefully chosen list concentrates each of them. Fewer medicines, better known, reliably supplied and affordably priced, treat the great majority of the conditions a population actually presents with, which is the empirical heart of the concept.

2.8 The concept of the essential drug: selection, lists and use

The concept works through selection and through disciplined use of the resulting list. Selection is by committee, on stated criteria, principally the pattern of disease, the treatment facilities and trained personnel available, genetic, demographic and environmental factors, and, medicine by medicine, efficacy and safety on the evidence, quality including stability in local conditions, cost and cost effectiveness, and a preference, other things equal, for single compounds with well known properties. The product of selection is a list, organised by therapeutic category, and the list then does work in the system: it guides procurement and supply, concentrates training and information, anchors the formulary of institutions, informs prescribing guidance and reimbursement, and gives the public a visible standard of what the system undertakes to provide. Lists are revised periodically because evidence, resistance patterns, prices and disease patterns change. The list is a floor for access, deliberately: it guarantees the medicines of greatest need; it does not claim that no other medicine should ever exist, and arrangements for exceptional need sit beside it in a well run system.

Essential medicines: from need to guided use



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Figure: From population need to a working list. Selection is the concept; supply and guided use are where it succeeds or fails.

2.9 National essential drug policy and list

A national essential drug policy is the medicines component of national health policy: the government's stated commitment to selection, availability, affordability, quality and rational use, expressed through the national list and the systems that stand behind it. In India the corresponding instrument in current usage is the National List of Essential Medicines, prepared and revised through an expert committee process under the health ministry, which states which medicines the Indian system treats as essential for its priority needs. The policy and the list work together: the policy supplies the principles, procurement and pricing attention,

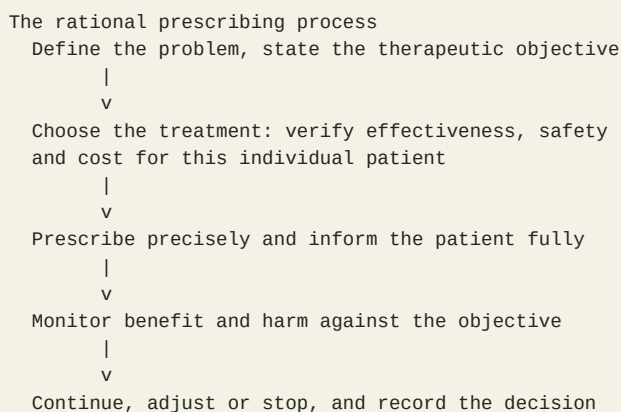
quality assurance and promotion of rational use, and the list supplies the concrete content those principles act on. These notes state no edition, count or contents of any list, deliberately: lists are revised, and the professional habit taught here is to work from the current list itself, checking a medicine's presence, form and conditions at the time of the decision. For the examination, the answer structure is definition, selection criteria, functions of the list in supply, training and prescribing, and periodic revision.

2.10 Rational drug use: definition, concept and need

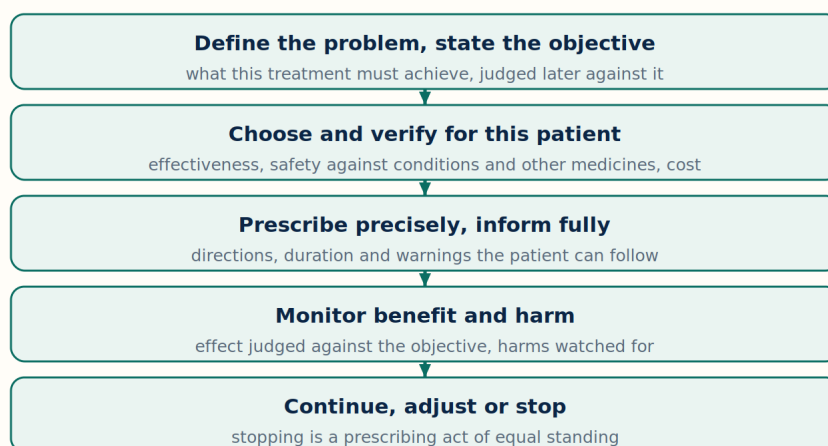
Rational drug use, in the classic World Health Organization formulation adopted at the Nairobi conference of experts, requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community, with dose here taught qualitatively as individual requirement and never as figures in these notes. The concept is the prescription level twin of QUM: QUM names the whole quality endeavour, rational use names what a single course of therapy must satisfy to belong to it. The need arises from the observed opposite, irrational use in its recognised forms: too many medicines per encounter, a medicine where none is indicated, an antimicrobial where the condition does not call for one or chosen without regard to guidance, injections where an oral form would serve, prescribing that departs from guidelines without reason, and self medication with prescription medicines or in unsafe ways. Each form wastes money, adds avoidable risk, and, for antimicrobials, spends a shared resource, continued effectiveness, that no individual prescription can restore. Rational use is thus simultaneously a clinical, an economic and, for antimicrobials, a community duty.

2.11 Rational drug prescribing: the prescriber's process

Rational drug prescribing is the process that produces a rational prescription, and it is taught as an ordered discipline. The prescriber first establishes the patient's problem and states the therapeutic objective: what this treatment must achieve, in terms the outcome can later be judged against. The choice of treatment follows, verifying, for the chosen medicine, its suitability for this patient: effectiveness on the evidence and in guidance, safety against this patient's conditions, other medicines, allergies and physiology, and cost the patient and system can sustain. Prescribing is then executed precisely: the right product and form, clear directions, duration and quantity matched to the objective, and warnings stated. The patient is informed, in the counselling sense of Unit 1, because a prescription the patient misunderstands is irrational in effect however rational on paper. Finally the result is monitored: benefit judged against the objective, harms watched for, and the medicine continued, adjusted or stopped on that judgement, with stopping recognised as a prescribing act of equal standing. The familiar shorthand for the whole process, right drug, right patient, right dose in the qualitative sense, right route, right time and right documentation, is a memory aid for this process, not a substitute for it.



The rational prescribing process



A prescription the patient misunderstands is irrational in effect

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Figure: Rational prescribing is a cycle with a stop decision inside it, not a single act of writing.

2.12 Role of the pharmacist in rational drug use

The pharmacist promotes rational use at every point where a prescription can still be improved. At prescription review, before supply, the pharmacist checks indication against medicine, the choice against formulary and guidance, interactions and duplication across the whole list, and suitability in the special populations of Unit 3, and intervenes with the prescriber on what is found, constructively and with evidence. At dispensing, accuracy and labelling protect the written intention from execution error. At counselling, the pharmacist converts the prescription into the patient's own practice, which decides its real effectiveness. Beyond the individual prescription, pharmacists build the system that makes rational use normal: formulary and drug information work, prescribing feedback and evaluation of the Unit 1 kind, antimicrobial guidance work inside the hospital team at the general principle level of this syllabus, education of prescribers and patients, and pharmacovigilance of Unit 5, whose reports are rational use learning in its sharpest form. The role is therefore both checkpoint and architect: intercepting the irrational prescription today while helping design the service in which fewer are written.

Concept	Level it works at	Core question it answers	Pharmacist's main instrument
Evidence based medicine	The decision	Is this choice justified by the best evidence, read critically?	Appraisal, guidelines, drug information
Essential medicines	The health system	Which medicines must always be available and affordable?	Formulary and list based supply and guidance
Rational drug use	The individual prescription	Does this patient get the appropriate medicine, suitably, for long enough, at lowest fair cost?	Prescription review, counselling, monitoring

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