EDITORIAL

Beneath, Behind, Besides and Beyond Evidence-Based Medicine

JOSEPH L MATHEW

Advanced Pediatrics Centre, PGIMER, Chandigarh. jlmathew@rediffmail.com

This issue of *Indian Pediatrics* marks the completion of two years of the EURECA (*E*vidence that is *U*nderstandable, *R*elevant, *E*xtendible, *C*urrent and *A*ppraised) section, presenting evidence summaries on relevant clinical problems(1). The overall response from colleagues in India and abroad has been very encouraging. Therefore, it is pertinent to examine some related issues here.

It appears that the initial resistance/scepticism towards evidence-based medicine (EBM) has declined and the current challenge for professionals is "how to" rather than "why to" practice EBM. The major hurdles include limitations related to: (*i*) availability (of high quality evidence on problems/ interventions relevant to our setting), (*ii*) accessibility (to current evidence at the point-of-care), (*iii*) appraisal (of available evidence to judge reliability/validity), and (*iv*) applicability (of evidence developed for/from another setting into the local setting). The sterling contribution of the Cochrane Collaboration worldwide and the South Asian Cochrane Network (now Centre) in India have greatly facilitated progress towards overcoming these barriers.

BENEATH EBM

The foundation of evidence-based medicine is evident (pun not intended) from its definition, which is the "integration of best research evidence, with clinical expertise and patient values"(2,3). Three important points should be noted to avoid misperception. (*i*) 'Best' research evidence implies systematic identification, critical appraisal (of methodology) and synthesis of scientific literature; not merely searching for (and citing) randomized controlled trials or systematic reviews to support a given action/decision/guideline/recommendation. The latter avoidable error unjustifiably tarnishes the principle and process of EBM. (*ii*) Clinical expertise is integral (rather central) to effective health-care; EBM reinforces expertise with best research evidence. Therefore 'evidence-based' is not distinct from 'experience or expertise based', but complementary. (*iii*) 'Patient values' include the unique circumstances (such as health-care setting, personal/social issues, etc) of individual patients for/ by whom health-care decisions are made. This concept also facilitates shared (patient-professional) decision-making which is a goal of health care.

Despite tremendous progress in the production, appraisal, and access to the best research evidence; understanding of patient values has lagged in developing countries where health-care is often 'provider-driven' with a 'take-it-or-leave-it' attitude. Attempting to apply best research evidence, bypassing/ignoring patient values can do more harm than good, a fact that needs to be recognised when 'best evidence' from other settings is directly extrapolated to the local health-care setting. Paradoxically, a shared decision not to apply best research evidence on account of patient values, can also be regarded as sound evidence-based medicine.

BEHIND EBM

Despite its numerous strengths, a potential limitation of EBM is that 'health-care interventions' (therapeutic/diagnostic) rather than 'health

problems' are the usual starting point for generating research evidence, whether primary (comparative trials) or secondary (systematic reviews). In other words, while EBM tries to answer "Does X intervention work for Y clinical problem?", it does not directly address the more important issue of "What's the best approach for Y clinical problem?" For example, EBM can answer "Is hepatitis B vaccination efficacious?" but not "What's the best approach to control hepatitis B in India? (choosing from one or more of - universal vaccination, selective vaccination, health education strategies, treatment of cases, screening, etc)." The latter question is more complex, but necessary to make appropriate decisions. One of the reasons that research revolves around interventions is that industry produces and markets a variety of products that need to be evaluated.

BESIDES EBM

Evidence-based practice necessitates that 'best research evidence' itself be critically appraised to judge validity, clinical significance, and applicability. There are currently a host of tools for appraisal of validity based on methodological quality of research and evaluation of sources of bias (systematic error). However, judging clinical significance of research findings requires expertise and experience. Assessment of applicability is perhaps the toughest component and requires judgment of several factors described below.

Often (primary and secondary) research does not provide conclusive evidence on all the outcomes relevant to multiple stakeholders. Taking the example of hepatitis B vaccination, the decision to initiate vaccination does not depend on evidence of efficacy (*does it work?*) alone. Other issues like safety (short and long term), cost, cost-effectiveness, feasibility, comparison with other possible interventions, etc need to be factored-in, to make an appropriate decision. Consideration of these factors together adds up to evidence of effectiveness (*will it work in this setting?*)(3). Further, the outcomes determining 'effectiveness' could vary among different stakeholders. For hepatitis B, the main outcome of interest for health-care professionals could be prevention of hepatitis B and its complications; for policy-makers could be cost-effectiveness, feasibility and prioritization against other health-care needs; for 'consumers', the guarantee of individual protection, freedom from side effects and convenience. 'Best' research evidence usually does not address all these complex but important issues. The additional problem is that research often presents secondary/surrogate outcomes, that are expected to correlate with the main outcomes of interest (for example hepatitis B surface antigen evaluated in most trials is a surrogate marker for hepatitis B infection diagnosed by histopathology). The extent to which various secondary outcomes actually reflect the primary outcome of interest, necessitates critical judgment. Based on these facts, it is easy to appreciate that highly objective 'evidence of efficacy' should be superseded by 'evidence of effectiveness', which could have an additional subjective component. Therefore there has been a gradual shift from 'evidence-based medicine' towards a more practical concept of 'evidence-informed health-care/decision making'; which is based on more than systematic reviews of efficacy/safety.

BEYOND EBM

The various components that together facilitate informed decision-making comprise the discipline of Health Technology Assessment. Although it sounds like a misnomer, "health technology" is a loose term covering all methods used to promote health, prevent or treat disease and improve rehabilitation or long-term care(4). My own definition includes eight Ps *viz* the Products, Practices, Procedures, Processes, Programs and Principles that Promote health or Prevent disease. Health Technology Assessment (HTA) is the scientific process of examining the medical (efficacy, safety), economic (cost, cost-effectiveness), social, logistic and ethical aspects pertaining to the application of a given health technology. It has been described as a bridge between health-care research and real-world decision-making(5). The final product of HTA is a document that 'informs' various stakeholders. Most developed countries have well-established HTA units/organizations/institutions that guide individual /community/national policy in their setting. This is deficient in developing countries, where competing

priorities for limited resources demands that health-care decisions be based on robust scientific principles.

THE WAY FORWARD

The leadership position of the Indian Academy of Pediatrics and the prestige of *Indian Pediatrics* makes them natural vehicles to foster a culture of evidence-informed healthcare in India. Some of the practical ways this can be achieved are:

- Promoting understanding of the concept and process of EBM, HTA, and evidence-informed health-care among professional colleagues, and medical students.
- Providing training opportunities to develop critical appraisal (of literature) skills and tools to understand and assess the validity and applicability of scientific literature.
- Developing evidence-informed guidelines and recommendations for diagnosis, management, and prognostication of common clinical conditions along the EURECA criteria.
- Expanding the above dimensions to include all partners in healthcare viz policy-makers, other healthcare professionals, patients/consumers, industry, and health advocacy groups.

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