

ARCHIVES OF DISEASE IN CHILDHOOD

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Annotations

Future prospects for evidence-based child health

How will the evidence-based health care movement be seen in the future? A passing fad as clinicians again embrace the ‘art of medicine’? Enthusiastically adopted and institutionalised with central directives determining clinical decisions? Or, as the hyperbole fades, will it become viewed as just one of the essential tools that clinicians use in their day to day decisions?

A passing fad?

Is evidence-based health care just a passing fad, promoted by managers and purchasers enjoying their influence over clinical practice, but doomed to fail as a far too cumbersome method for dealing with the complexity and imprecision of real life clinical decisions? Critics argue that the emphasis which evidence-based health care gives to experimental evidence devalues important immeasurable factors¹ (the ‘art of medicine’) and ignores the importance of caring and supportive clinicians who constitute much of what the health service has to offer.²

Few would argue against a humane health care system that treats people as individuals rather than a risk category. However, such a system needs to meet patients’ expectations and rights to be fully informed about their clinical care, even if they decline to participate in decisions. Moreover, there may be a therapeutic benefit in their knowing what to expect.³ Most importantly, patients want clinicians who know (rather than believe) whether a treatment will work or not. And if we don’t expose the evidence on which decisions are based, we might get it wrong, both by failing to maximise benefits for patients (and society) and failing to highlight the inadequacies of existing research.

Clinicians working in maternal and child health are only too well aware of examples where we have got it wrong: the 20 year delay from the first randomised controlled trial to the routine use of antenatal steroids for women in preterm labour, which substantially reduce the risk of neonatal death⁴; the advice given by health professionals over two decades to put babies to sleep prone that increased, rather than reduced the risk of cot death⁵; and the 25 year delay in adequate evaluation of sight saving treatment for retinopathy of prematurity.⁶

Overtaken by directives?

What is the most efficient way of making sure that we don’t get it wrong? If the evidence is available, surely what is needed is for someone to evaluate and summarise it in plain English and use the results to direct clinical decisions in whatever ways have been demonstrated (in randomised controlled trials (RCTs)) to most effectively change clinicians’ behaviour? Fortunately, there is a growing research literature on the effectiveness of interventions in changing clinical practice. Methods for directing or reminding clinicians top a heterogeneous list which includes: computer reminders, patient mediated interventions (for example educational material or reminders), opinion leaders, academic detailing (like pharmaceutical company representatives), audit and feedback and guidelines with rigorous evaluation.^{7–9} Conferences have been found to be ineffective in this league table of interventions to change specific practices.

Should more clinical decisions be determined by directive approaches? Where the decision is straightforward (for example whether or not to give antenatal steroids), the evidence on which it should be based is incontrovertible, the balance of harm and benefit clearly established,¹⁰ and clinicians are still not offering interventions of proved benefit, then directive methods are likely to be most appropriate. Guidelines are a widely used method but are most credible if they are explicit about the evidence on which they are based¹¹ and about the values attributed to the various outcomes.¹⁰ Greater consistency in guideline recommendations¹² and the specification of absolute risk differences for different patient groups would increase their usefulness. Purchasers and managers can play a major part in determining the quality of service by promoting and monitoring implementation of such interventions, and by devising imaginative strategies that take account of social influences and keep clinicians receptive to this ‘top down’ approach.¹³ One way may be to extend their role. For example, guidelines for the screening and treatment of retinopathy of prematurity were launched in conjunction with a nationwide programme of training, audit, and research.¹⁴

Uncertain evidence

What are the other clinical decisions that are common, clinically important or of high cost, which meet the criteria

of being based on incontrovertible evidence and are not already practised on a sufficiently wide scale?

The main problem is that incontrovertible evidence is rare. In reality, most clinical and policy decisions are based on evidence of varying degrees of uncertainty.¹⁵ Will there be more incontrovertible evidence in the future or will increasing knowledge lead to greater uncertainty? The latter seems more likely. The more we know about options for intervention and about the potential for benefiting or harming patients, or for increasing or reducing costs, the more complex are the decisions about who could or should benefit. In addition, as the pace of change of knowledge and technology accelerates, less of our practice will be based on 20 years worth of controlled trials, as the interventions evaluated are replaced by new developments.

The second problem is that sometimes, neither research (systematic reviews included) nor guidelines are able to address the questions that patients and clinicians really need to answer in order to make clinical decisions. For example, an excellent overview on the treatment of persistent glue ear in children recommended adoption of a 'watch and wait' policy instead of grommet insertion.¹⁶ Three RCTs, based on children with bilateral glue ear who had grommets inserted in one ear with the other ear acting as a comparison, were particularly informative to this recommendation. The studies showed that improvement in hearing deficit was less than 12 decibels at six months and less than 6 decibels at 12 months after grommet insertion. However, the authors highlighted important gaps in evidence. For purchasers, information was lacking on the costs of a watch and wait policy compared with surgery. For parents and clinicians, the effects on language development and behavioural outcomes were not known.

What does evidence-based health care have to offer?

If the evidence underpinning most clinical decisions is so uncertain, does evidence-based health care have anything to offer clinicians? We believe it does. Firstly, it starts with the clinical problems faced by patients and clinicians and the decisions to be made rather than starting with the existing evidence researchers have chosen to generate. Inevitably this means that, for some questions, the evidence may be far from adequate, but will nevertheless be the best available on which clinicians and patients are able to base their decisions.

Secondly, evidence-based health care provides a way of breaking down complex decisions into their component parts, so that the evidence for the predicted outcome of a diagnostic test, treatment, or exposure can be examined separately from value judgments about what outcomes are preferred—whether for reasons of individual preference (patient or clinician), costs, or service pragmatism. Scientific evidence thereby informs decisions that are finally determined by clinicians, patient, clinical team, purchasers or management, whose value judgments are mostly made intuitively, but can be measured more formally.^{17 18}

Thirdly, evidence-based health care emphasises the need to base decisions on evidence which shows what actually happens to patients rather than draw conclusions by extrapolation from observations at a molecular, cellular, or organ level.

Evidence-based health care has been defined as the 'conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'.¹⁹ It can be summarised as a decision making process that involves five steps:

- (1) Framing answerable questions from clinical or policy problems
- (2) Searching for the evidence (whether from research, clinical observation, or one's own practice)

- (3) Appraising the evidence for its validity (closeness to the truth) and usefulness (relevance to the patient problem)
- (4) Pending how to implement the findings of this search and appraisal into practice
- (5) Evaluating the change in practice.

An example

Here is an example of how evidence-based health care can work in practice: suppose you are confronted with a 3 year old child with mild croup in the accident department at 10 pm. The decision seems to be whether to admit or send the child home, but you think of another option, and a question. Answerable questions are best structured in three parts: the patient population, the intervention or exposure and, where relevant, a comparison group, and the most relevant outcome. Your question is: 'In children with mild croup seen in the emergency department... (the patient population), ...does one dose of nebulised budesonide compared with no treatment... (the intervention and comparison group)... reduce the chance of admission to hospital? (the clinical outcome)'.

Use of a simple decision tree to map out the decision may prompt consideration of other questions. For example: 'in patients with mild croup does oral dexamethasone compared with nebulised budesonide reduce the chance of admission to hospital?' A further advantage of a decision tree is that, as absolute risks have to be allocated to the outcomes (for example chance of being admitted is 26% with placebo and 4% with nebulised budesonide²⁰), this can sometimes make the balance of costs and benefits immediately obvious. A disadvantage is that decision trees can become complicated.

Spending time getting the question right is worthwhile as it guides the next steps.²¹ As this is a question about an intervention, first choice would be to look for a RCT, for example, using Medline. Having entered in croup, budesonide and 'clinical trial in pt', you can scan the abstracts to pick out those which refer to a similar population—those with mild to moderate croup, with hospital admission as an outcome. To help with the third step, appraisal of the evidence, excellent, readable guides have been generated by the Evidence-Based Medicine Working Group at McMaster University.²²⁻²⁹

Such a Medline search on the question of budesonide compared with placebo generated three studies, one of which involved children with mild to moderate croup and recorded hospital admission as an outcome.²⁰ Fifty four children were given either nebulised budesonide or nebulised saline. A quick check on the validity confirmed that clinicians were blind to randomisation, follow up was complete in both groups, an intention to treat analysis was carried out, clinicians and patients were blind to treatment, and the groups were similar at the start of the trial. The reduction in the risk of admission was 22% (one admission prevented for every 4.5 children treated: 95% confidence interval 2.5 to 25). These findings were supported by a greater reduction in the croup severity score in treated children. Two other RCTs demonstrated a benefit of nebulised budesonide over placebo for moderate to severe croup,^{30 31} and one of these showed similar outcomes for children treated with oral dexamethasone or nebulised budesonide.³¹

This evidence is far from certain but is the best available at 10 pm in the accident department. So how certain do you need to be? Clinicians need to be cautious about adopting findings from just three studies (as the results may have occurred by chance or be biased), and some clinicians (sometimes referred to as laggards³²) may decide to wait for further evidence. Others may decide that the risks

of adverse outcomes are low, that there is supportive evidence of the benefit of steroids in severe croup, including a meta-analysis of trials,³³ and that overall benefits outweigh costs. There is no right or wrong decision and health care is probably best served by a mix of reflective 'innovative' and 'laggardly' clinicians.³⁴

If this sounds like dodging the issue, consider the possible advantages of this exercise. The clinician has questioned standard practice and checked up on whether more effective treatment exists; the potential benefits of treatment and uncertainty of the evidence have been made explicit for the parents and clinicians involved; and lastly, members of the team can scrutinise whether this is the best available evidence and highlight the need for further information. For example: review policy when further RCTs are reported, particularly comparing oral dexamethasone with nebulised budesonide; search out the evidence on the risk of adverse effects of nebulised budesonide.

Getting evidence-based health care into the system

Undoubtedly, evidence-based health care is a daunting task for busy clinicians and managers to undertake for all the decisions they make. Organisations need to look at ways in which clinicians can be helped to help each other admit their lack of certainty, prompt and address questions about the evidence underpinning practice, and to support implementation and evaluation of practice. Fragmented work patterns and devolution of care works against such interchange and further reduces the opportunities for clinicians to have feedback about the outcome of their decisions.³⁵ One approach is to harness existing practice evaluation and continuing education sessions more fruitfully (for example journal clubs, grand rounds) so that common, important decisions are reviewed, and the evidence underpinning them evaluated in a systematic way. Such clinical evaluation could draw much more on service evaluation (audit, outcomes measurement, budget monitoring) to generate questions, provide information about local practice and support evaluation of implementation. Together, continuing education and practice and service evaluation activities could contribute much more to effective health care than their separate parts.

Developments in information technology and the published literature can make evidence-based health care easier and offer some short cuts. Access to on-line search facilities at the work site is available to a growing number of clinicians and managers and developments in the use of search filters can help make searching more efficient.³⁶⁻³⁹ Others may have already appraised the evidence.⁴⁰ For example, secondary publications of research articles in the *ACP Journal Club* and *Evidence-Based Medicine*, publish summaries of articles that meet certain quality standards. The Cochrane Collaboration and York Centre for Reviews and Dissemination have set high standards for overviews and stimulated rapid growth in the number of overviews of research (now available on disk or CD-ROM⁴).

Conclusion

How will evidence-based health care be seen in the future? For those who hoped it would provide gold standard answers, our view may be unsettling. However, incontrovertible evidence is rare, and clinical decisions complex, which is why clinical care is provided by clinicians not technicians. Evidence-based health care cannot change this but may become a useful tool to help individual clinicians weigh up the evidence for themselves so that they can share the information with patients and incorporate patients' values and preferences in their clinical judgment. Exposition of the evidence underpinning clinical practice may also facilitate informed participation by non-clinicians in

decisions about rationing. Finally, evidence-based health care provides a way for clinicians to articulate their priorities for research and thereby contribute to setting a research agenda which is more relevant to service needs.

Does evidence-based health care really help clinicians provide more effective health care? The evidence is uncertain,^{41 42} but no doubt, more studies will be published over the next few years. However, given the complexity of clinical practice, one intervention is unlikely to be effective on its own. Evidence-based health care is one component of an evaluative culture to which developments in information technology, research—particularly the generation of overviews—and organisational factors also contribute.

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Integrated management of childhood infections and malnutrition: a global initiative

Global childhood mortality

Twelve million children die each year before they reach their fifth birthday. The majority (70%) of these deaths are due to diarrhoea, pneumonia, measles, malaria, or malnutrition—and often to a combination of these conditions. Moreover, these conditions typically account for three out of four sick children seeking care at a health facility.¹

Acute respiratory infections (ARI) are the leading cause of mortality in children worldwide, causing one third of all child deaths in 1993 (approximately four million).² Deaths from ARI are mainly due to bacterial pneumonia.²⁻³ Some three million diarrhoeal disease episodes in young children resulted in death in 1993, accounting for 25% of child deaths. Globally, 50% of these deaths were due to acute watery diarrhoea, 35% to persistent diarrhoea, and 15% to dysentery. Measles and malaria are estimated to be associated with 10% and 8% of childhood deaths respectively. The latest World Health Organisation (WHO) estimates state that malnutrition is associated as an underlying cause with 54% of all childhood deaths, an upward revision from the earlier estimate of 29%.¹

Low birth weight, suboptimal breast feeding practices, malnutrition, and maternal behaviour influencing child care are important risk factors associated with increased incidence and severity of these diseases. The most important environmental risk factors are indoor air pollution for pneumonia and inadequate water supply and sanitation for diarrhoeal diseases. HIV infection is an additional risk factor of growing importance.⁴⁻⁵

Need for an integrated approach to the management of sick children

Almost all developing countries have reported reductions in child mortality in the last 10 years. The United Nations estimates that 13.3 million children under 5 years of age died in the developing world in 1985, and 12.2 million died in 1993.⁶ This represents a decrease from 117 deaths per 1000 live births in 1985 to 97 in 1993. Much has been learned from disease specific control programmes such as those tackling diarrhoeal disease and ARI in the past 15 years.⁷⁻⁸ However experience in developing countries with high child mortality has shown that children presenting with severe illness often have multiple disorders and dem-

onstrates the need for a more comprehensive approach to the assessment and management of sick children that ensures prompt recognition of septicaemia, anaemia, malnutrition, and malaria as well as dehydration, dysentery, persistent diarrhoea, and pneumonia. The challenge is now to combine these successful approaches to ARI and diarrhoeal disease case management and extend them to include the clinical management of malaria, measles, meningitis, and malnutrition. The WHO and the Unicef have responded to this challenge and developed an approach based on the integrated management of the sick child. These efforts involve some 12 programmes within WHO and are coordinated by WHO's new Division of Child Health and Development.

Developing integrated case management guidelines

Integrated guidelines for management of the sick child have been developed through a process of review of existing disease specific guidelines, systematic literature review, clinical and health systems research, and field testing. The guidelines promote an approach to clinical management that is appropriate for first level outpatient facilities such as health centres in developing countries. Diagnosis is not dependent on laboratory tests but instead is based solely on valid yet simple clinical signs which health workers from various backgrounds can be trained to recognise accurately. Experience in a number of developing countries has shown that this approach results in health workers making clinical decisions about the management of sick children that accord closely with the independent assessments of experienced paediatricians (WHO, results of Arusha field test, 1995; unpublished).⁹⁻¹¹ This approach combines several child health interventions. There is evidence of their effectiveness in reducing mortality from community based intervention trials (for example case management of ARI, vitamin A administration, and measles immunisation), clinical trials (for example vitamin A treatment in measles), or from observations of decreased case fatality rates after the implementation of standardised guidelines (for example treatment of severe malaria and diarrhoeal disease).¹²⁻¹⁵

The case management guidelines that have been developed are targeted at health workers in busy health centres and outpatient departments of small hospitals. In many circumstances these will be medical assistants, para-