Quality in healthcare – Part 4

Clinical effectiveness, evidence-based medicine, cost effectiveness

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In our daily lives whenever we purchase something, be it a mobile phone or a washing machine, we want to be sure that it actually **does** what it is supposed to do, and that it is worth what we pay for it. And yet – isn't it amazing that we never bothered to apply the same checks to something as important as healthcare, until relatively recently?

We blithely carried on with established procedures, on the basis that we have *always* done them so, and so had our teachers and theirs; so surely they **must** work. (e.g. D and C for heavy periods). Whenever there was a new exciting procedure, we merrily jumped on the band wagon without asking too many questions, especially if it had been developed in a prestigious unit. (e.g. routine continuous intrapartum electronic foetal monitoring).

Things began to change in early 90s, when the cost of healthcare came under political searchlight. Questions were asked. The simplest definitions to the first two of the above themes are answers to two simple questions:

1. *Does it work?*
2. *How do we know?*

Although the questions seemed simple and straight-forward, finding the answers was not.

At a glance, D and C did reduce heavy periods in the **short** term; women told us so at the 3 month review. So, it would be recorded as 'cure' or 'success'. However, consistent long term follow up data were not available. Hence to answer the question properly and fully, carefully planned longer term studies were required.

Similarly in other areas, good factual evidence was hard to come by. There was an urgent need to investigate what evidence is there already and to assess its quality, and where necessary to suggest areas for further research. Hence, the concept of *Evidence-based medicine* was born, followed by professional guidelines, based on such evidence. Initially this was the domain of academic royal colleges, joined later by NICE.

'Evidence'

What constitutes evidence? What is 'good' evidence?

Evidence comes from published research data. Given the variation in the quality of such data, a system to grade them was necessary – hence the *hierarchy of evidence*.

Unfortunately different organisations use slightly different grading systems, but the basic principles are the same:

- interventional studies are stronger than observational;
- amongst interventional, randomised controlled studies are the best; in fact the 'gold standard';
- amongst observational, cohort studies are better than case-control;
- uncontrolled studies carry least weight.

Thus, in the hierarchical tree systematic reviews on RCTs reign at the top and anecdotal and experiential evidence, 'established practice', expert opinions are at the bottom, with others in between. Nowadays any new intervention would not be accepted as effective without RCT evidence – rightly so.

However, insisting on evidence for *everything* is not appropriate. One should not dismiss 'traditional practice' simply because one cannot find gold standard evidence from literature. When something is blindingly obvious, it would be wrong, even unethical to insist on evidence, for e.g.:

'Ergometrine is effective in preventing and reducing PPH';

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'Pethidine is effective in alleviating labour pains'.

(Unfortunately, this has not prevented some people from doing such research.)

On the whole, **method** of a given study is more important than the actual design. Thus, a well designed non-randomised study would provide more reliable evidence than a poorly done RCT. Sometimes randomisation is not practical or ethical.

Another problem is *'generaliseability'*. When it comes to practice, this is an important consideration. It is to do with the setting of the original research. Whereas something might work when done in a protected, well-resourced academic environment, would it work the same in the wider world?

E.g. 1: routine continuous electronic foetal monitoring in labour worked well in St Mary's, Paddington, but not everywhere.

E.g.2: cervical smear screening program works well in the UK, but very unlikely to do so in a low-resourced setting.

Assessing the available 'evidence' therefore is a complicated business. That is why Colleges and NICE have appointed expert committees to search for and assess all available evidence and give us an opinion on 'best available evidence' which form the basis of *guidelines*.

Cost effectiveness

Rolls- Royce is a very good car, but not everyone could afford one.

So, the next question is:

Is it worth it?

Once again, although the question looks deceptively simple, arriving at a considered answer is not.

The 'cost' is not only the direct financial cost of carrying out the intervention. Usually there are additional hidden costs. Not just personnel, overheads, etc, but cost of dealing with complications, including litigation costs. These should be added.

On the other hand, it is very important to appreciate that there is a cost of not doing it, for e.g. cost of treating cases of Rh isoimmunisation would be far greater than administering anti-D. Therefore, the cost of not doing it, should be subtracted.

'Cost' is not just financial. One must not forget the *human* cost of pain and suffering.

To compute all these complicated factors, the UK government established NICE to advise on various interventions (mostly new, some old). Although purportedly, 'E' stands for 'excellence', in truth it means 'cost'!

Conclusion

Although these quality parameters sound 'high-powered', the concepts are simple and no difference what we practice in every day life. The issue is the answers tend to be not that simple to arrive at. But that is not an excuse not to apply them to our practice, as the cost of not doing it is high, both in financial and human terms.