



- Patients who are potential haemopoietic transplant recipients should receive leucocyte-depleted components from inception of transfusion support.
- Intrauterine transfusions and all transfusions to infants under 1 year of age.

It should also be noted that there is little clinical evidence to support the routine use of leucocyte depletion filters for plasma.

Filtration should be carried out within 48 hours of collection, i.e. by the transfusion service. Bedside filters are not recommended since consistent quality control is not possible and older units will accumulate cytokines, etc. which may be responsible for some of the side-effects attributed to white cells. Obviously if individual clinicians believe that their patients

would benefit from leucocyte-depleted components for indications other than those above, they should naturally request this and the Services will issue accordingly. By monitoring the usage and gearing up accordingly the Services will be in a position to meet any such demands.

We trust that this clarifies the role of filters in the administration of blood components.

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PERSONAL VIEW

The payer and the piper – a view on evidence-based medicine

Hannes Loots

'He who pays the piper calls the tune' is a remark from the old German children's story *The Pied Piper of Hamelin*. Historically we can say that the tune has been 'the medical aid will pay'. Unfortunately, rising health care costs in the face of finite social resources have changed the tune to 'the medical scheme might not pay'. This tune might also signal the more important role of health cost management within the medical industry.

Until recently it was easy to view industry and medicine as separate entities. Medicine was a profession and industry a business. Medicine had patients and industry had customers. Today many consider medicine to be a business, the medical industry, with business rules applying. This has brought about sweeping changes. The number and intensity of clinical interventions is growing faster than ever before, and the expectations of a computer-literate society with its growing

concern for enhanced personal lifestyle are pressurising the primary aims of medicine. In a lecture presented at the Royal College of Physicians and Surgeons of Canada in Montreal during September 1999 the past president of the American Academy of Orthopedic Surgeons said the following: 'The medical profession is forced to consider medicine as the medical industry and areas such as medical education, research, hospitals, subspecialties, rehabilitation and investor-owned managed care have become branches of the medical-industrial complex.'

'Medicine has compromised professionalism to reap financial benefits. Physicians long considered that advertising and marketing themselves were inappropriate and demeaning. Today, many physicians freely use all available media to market themselves without shame or sanction. We have sold our birthright for a pot of porridge.'

Whether or not we as clinicians have sold our birthright to treat and cure patients is open to debate, but we need to accept and understand that the medical industry is indeed a new concept in many ways. This is an industry that talks about cost-effective health care, number needed to treat (NNT) as a

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measure of effectiveness of interventions, quality-adjusted life years (QALY), health technology assessment (HTA), evidence-based medicine (EBM) and evidence-based health care (EBHC), in contrast to basic health care and payment for services that we have understood up to now.

The term EBM might stir up reaction from many quarters in clinical medicine, and may need to be looked at in more detail. It is a tool used by many health risk managers to assess the appropriateness and cost-effectiveness of new techniques and procedures.

EBM is defined as the process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimal clinical care to patients.² It forms part of the multifaceted process of ensuring clinical effectiveness, the main elements being the following: (i) production of evidence through research and scientific review; (ii) production and dissemination of evidence-based clinical guidelines; (iii) implementation of evidence-based, cost-effective practice through education and management of change; and (iv) evaluation of compliance with agreed practice and patient outcomes.

All clinicians strive to provide the best possible care for their patients as required by medical ethics. However, given the multitude of research information available, it is not always possible to keep abreast of current developments or to translate them into clinical practice. One must also rely on published papers, which are not always tailored to meet the clinician's needs. Evidence is presented in many forms and it is important to understand the basis on which it is stated and furthermore to realise that EBM is available for relatively few interventions. The dilemma is also that current measures of some outcomes of medical treatment (such as pain) are inadequate, some (such as justice) may not be measurable, and other complex outcomes (such as quality of life) may not even be adequately definable.³

Managers of health care funds and clinicians both need to understand and accept the limitations of EBM, and make balanced decisions. All the relevant consequences of an action must be considered and all role players must be accountable for their decisions. The conscientious use of current best evidence in making decisions on the delivery of health services as well as the care of individual patients will eventually culminate in EBHC, which is perhaps where we ultimately want to be.

We may be tempted to ask what is best evidence if there are more than 20 000 biomedical journals and more than 2 million articles published annually.

Let us look at best evidence on the topic of lower back pain, for as Melzack said: 'Freedom from pain should be a basic human right'. Unfortunately the societal costs of back pain are three times higher than the total cost of all types of cancer, according to the Swedish Council on Technology Assessment in Health Care.⁴

Pain is a signal that something is wrong. Pain in the lower back affects up to 80% of all people at some time during life, while neck pain affects up to 50% of the population.⁵ In many cases pain is experienced as mild and only occasionally, with few people experiencing constant, persistent pain. The direct and indirect cost of pain is a matter of concern which we need to take cognisance of.

During the late 1980s the Swedish Council on Technology Assessment in Health Care initiated a project to review the scientific basis of methods used in health care and to evaluate their costs, risks and benefits on the diagnosis and treatment of back pain. This project has been continuously updated and 4 years ago an international project group of 13 people was appointed to assess results from scientific studies on the topic of lower back pain and neck pain published during the 1990s. This group selected 2 000 studies presenting relatively strong scientific evidence on different issues pertaining to back and neck pain. The studies were classified into groups reflecting strong, moderate, limited and no scientific evidence.

'Clinical Evidence', a compendium of the best available evidence for effective health care by the BMJ Publishing Group, published a similar report in December 1999.⁶

A summary of the results of systematic reviews from these and other publications^{4,6,8} highlights the level of evidence with reference to the current conservative (non-surgical) treatment regimens for lower back and neck pain as follows.

On diagnosis

Basic X-ray examination seldom provides guidance in diagnosis, except in cases where specific trauma or serious disease is present or suspected.

Computed tomography (CT) and magnetic resonance imaging (MRI) studies have the ability to visualise and confirm suspected specific disease. MRI is the most sensitive and specific investigation.

Only limited evidence is available for many other diagnostic methods and their benefits.

On conservative (non-surgical) treatment

'Many treatment methods are currently used, but there is little scientific evidence on their benefits. Some treatment methods are used despite scientific evidence showing that they do not benefit the patient.'⁴

For acute back pain

Strong evidence: (i) continuation of normal activities; and (ii) anti-inflammatory and muscle-relaxant drugs offer effective pain relief.



Some evidence: (i) spinal manipulation; and (ii) analgesics.

Unknown effects: (i) epidural steroid injections; (ii) facet joint injections; (iii) back schools; (iv) back exercises; (v) lumbar supports; (vi) transcutaneous electrical nerve stimulation (TENS); and (vii) acupuncture.

Ineffective or harmful: (i) bed rest; (ii) traction.

For chronic back pain

Strong evidence: (i) manual treatment/manipulation; (ii) back training/exercises; and (iii) multidisciplinary treatment programmes.

Moderate evidence: (i) analgesics; (ii) non-steroidal anti-inflammatory drugs (NSAIDs); and (iii) trigger point and ligamentous injections.

Unknown effects: (i) antidepressants; (ii) muscle relaxants; (iii) epidural steroid injections; (iv) trigger point and ligamentous injections; (v) lumbar supports; (vi) acupuncture; and (vii) TENS.

Ineffective or harmful: (i) bed rest; (ii) facet joint injections; and (iii) traction.

'Limited evidence suggests that epidural steroid injections are more effective than placebo for acute and chronic low back problems involving nerve root pain. There is no evidence on the effects of injections in trigger points, ligaments or facet joints.'⁴

'Strong scientific evidence shows that bed rest is not an effective way to treat acute low back pain. The previous perception that 1 to 2 days of bed rest is effective in treating uncomplicated, acute low back pain has been rejected in scientific studies.'⁴

On surgical treatment

'Strong evidence shows that surgical resection of herniated discs in patients with several weeks of pronounced lumbar root pain is effective.'⁴

'Persistence of back pain is not an indication for surgery. Laminectomy/discectomy are for nerve root compression with leg pain.'⁹

Conclusion

Costs as well as outcomes are driven by the way physicians practise medicine¹⁰ and clinical practice does not always follow published evidence. Practice variations could be significant across the country and often show little difference in clinical outcome. It is therefore necessary for medical schemes to design benefits in some instances that will fit in between standard practice and available scientific evidence. The problem is, however, that medical discoveries and marketing add costly new therapeutic options to the medical industry and that once adopted new technology by health care providers is difficult to discard. Of course, new technology and procedures can be beneficial and cost-effective as much as some old technology and treatment concepts can be just the opposite. In both these instances funding decisions often need to be made by health care funders to contain the cost of care by trying to increase the efficiency of the delivery of care and/or by rationing the amount of care provided¹¹ (and J J Nobel, unpublished lecture, December 1999).

If we cannot achieve an appropriate and cost-effective level of care based on clinical evidence, we probably have to conclude with the words of Carlo Levi, Italian doctor, painter, political prisoner and senator: 'The custom of prescribing some medicine for every illness, even when it is not necessary, is equivalent to magic.'¹²

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