

Kennedy Review on how NICE values innovation

An RCN response

Introduction and Background

With a membership of over 400,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

NICE commissioned Professor Sir Ian Kennedy to conduct a short study on valuing innovation. The study will look at:

- What approach should be adopted by NICE to ensure that innovation is properly taken into account when establishing the value of new health technologies?
- Should particular forms of value be considered more important than others?
- How should innovation in health technologies be defined?
- What is the relationship between innovation and value?

Evidence would be gathered through:

- written submissions
- workshops with interested parties
- the NICE Citizens' Council meeting at their in May 2009

A report will be prepared for the NICE Board to consider at its public meeting in July 2009.

Executive Summary

In what follows we take “innovation” to refer to new and different approaches to treatment, rather than just referring to ‘any’ new technology. There is a sense in which any new drug or technology is an innovation, even if it is no more than a modest improvement on other drugs of the same general type.

Innovative approaches that involve a departure from previous therapies by definition lack a body of knowledge and experience in clinical practice and the potential long term benefits of a new approach can only be assessed over the long term. Innovative approaches to therapeutic and interventional procedures should nevertheless be encouraged and scoped with a more proactive long term approach to supplement data that will eventually inform further reviews or guidance.

New therapeutic options should be targeted by NICE in the context of what treatments are already available for the condition and whether the ‘new’ treatment will improve the body of knowledge in some way.

Using this approach could help NICE shift focus to other areas of care in which there is a clear need for innovation but where perhaps current funding and attention to R&D is sparse. In that sense NICE could have a role for encouraging a broader R&D industry in healthcare.

Innovation could be encouraged through some weight or flexibility being given to therapies or technologies that are introduced where there has been little or no prior innovation or limited treatment options, against those that have a plethora of treatment options already in place.

A practical option with regards encouraging the development of an evidence base in new therapies or treatments could be for NICE to allow clinicians and purchasers of care limited or probationary access to a new treatment or technology; allowing such access to be based upon an informed decision making and detailed review of benefits (clinical research options).

When new therapies are being reviewed, consideration should also be given to treatments that the new therapy should displace (particularly where there is limited or no evidence to support treatment – based upon new value system). However, an incremental increase in evidence around one therapy over another is not in and of itself reason to discontinue a particular therapy. Care must be taken not to throw out the old for the new too readily. A broader definition of value (which must include public, patient, professional and political perspectives) would assist in that evaluation as would balancing the QALYs and value systems that positively discriminate against individuals with a long term disease. The potential to be costly over a lifetime is high but this fails to be adequately captured in current real case scenarios. Wider evidence needs to be considered in the context of direct costs and a greater weight given to indirect costs which should include a broader definition of health, need and value.

In any event decisions to discontinue other treatment options could be a phased event rather than stopped altogether to ensure longstanding recipients are not left having to adjust to the loss of a treatment which might have worked very well for them in maintaining and improving the quality of life.

More consideration needs to be given to what drives or *should* drive innovation. The role of patient, industry, professional and political groups in steering developments in therapies needs careful consideration. The value of innovation needs to be described from a range of perspectives and we need to be careful not to over emphasise one view over another bearing in mind the long lead in time from innovation to delivery of a product or therapy. In short a range of values and costs including indirect costs to the patient and society must be more adequately scoped and considered.

1. What approach should be adopted by NICE to ensure that innovation is properly taken into account when establishing the value of new health technologies?

- 1.1. When addressing the above, it is important to consider the value of innovation in clinical practice standards or pathways as well as the value of health technologies. Innovation in practice has the potential to increase effectiveness of existing therapies through better patient compliance or alternative delivery routes or through combining the work of different disciplines. There are already a range of low cost initiatives which could enhance compliance and therefore enhance the cost effectiveness of drug and other therapies – NICE could have a role in promoting or evaluating these initiatives through guideline development.
- 1.2. The difficulty facing advocates of innovative approaches is that, by definition, there is a lack of a cumulative body of evidence and experience in clinical practice fully to understand the potential benefits of a novel approach. These benefits may extend beyond simple therapeutic benefits to a deeper understanding of the pathology and natural history of the condition.
- 1.3. The approach undertaken by the specialists within the field of rheumatology for example benefited not only the evidence base in relation to new technologies but also enhanced knowledge about immunological pathways and future therapeutic options. The British Society for Rheumatology provided one model of responsible specialist use of innovative new therapies with the Biologics Register. However this was a significant administrative and financial burden and is not transferable to all specialists within the NHS. NICE should consider how the wealth of true clinical practice can be adequately captured to represent the 'routine' aspects of clinical care and complex patients.
- 1.4. Evidence in a rapidly evolving field of practice should be adequately considered or captured. For example a proactive approach on future data collection could consider *hypothetical* improvements following the introduction of a new technology. An example of this is that of Rheumatoid Arthritis therapies. Radiological progression appears to be reduced when patients are proactively managed with TNF blockers– yet it is still an area of contention because evidence has not been reviewed in areas such as reduction in joint replacement under taken by the National Joint Registry.
- 1.5. It is accepted that there may be some limitations in this type of evidence. They are the early indicators of change and should in some way have some value against the double blind randomised controlled trial approach. It may not be possible in a five year period to see early indicators of reductions in patients treated with biologics but certainly setting the right data collection in place early on would mean that in 10 years time this evidence would be available. If this approach had been considered at the beginning of the introduction of these therapies a substantial evidence base would now be available.
- 1.6. Innovation and treatment options are an area of intense interest for patients particularly those that have been waiting many years for improved treatment options. It seems that when further evidence is needed and patients wish to

be considered for the treatment, they currently have few rights to make a decision to receive treatment – unless they participate in clinical research trials.

- 1.7. Current cost effectiveness data positively discriminates against patients with long term conditions. A recent Health Service Journal Report (5th February, 2009) highlighted the fact that NICE values some lives more than others. NICE places considerable value on ‘treatments which offer the possibility of extending life when we are close to death’.
- 1.8. When new treatments or technologies are being considered, a natural consequence should be a consideration of what it might replace. Where there are concerns over current approaches or a very poor evidence base, existing options should be reviewed and recommendations made about removal of less effective approaches.
- 1.9. This would have the *potential* effect of raising the quality of care and reducing wasted costs on therapies that have limited or no value to patient care. However when removing less effective therapies, care should be taken to transition from one care pathway to another to ensure that every step has been taken to inform and assess any impact from a range of perspectives including the patient’s.
- 1.10. A broader evaluation of future benefits from new technologies should be considered to encourage the appropriate on-going clinically relevant evidence. Innovation should be considered in the context of improving the body of knowledge particularly where therapeutic options and routes of treatment are currently limited.
- 1.11. NICE should therefore develop a new approach to the assessment of innovative therapies that allows, at least for a reasonable period, a more flexible approach to funding decisions that take into account the possibility of broader gains in our understanding of a condition and its associated therapies and management. These funding decisions could take place at a more local level; a level which NICE could support through supplying evidence and support. The RCN has already endorsed a more consistent form of decision making at local level in its response to Prof Richard’s review of private prescriptions in Cancer care¹.

2. Should particular forms of value be considered more important than others?

- 2.1. Present approaches to the assessment of value are overly simplistic (as are definitions of health which in reality should consist of a wide range of characteristics including personal and social care, accommodation, finance, education, employment and leisure, transport and access).
- 2.2. In addition, quality of life is a complex concept and cannot easily be reduced to quantitative measure on an interval scale. Perceptions of the value of improvement in, for example, symptom control and the sufferer’s experience of duration mean that what is objectively a small gain in function for a

¹ RCN (2008) ‘Top up payments in Cancer Care’. RCN Policy Unit. London

relatively short time may be perceived as of considerable value for the patient. QALYs make no allowance for these factors.

- 2.3. The cost element of the QALY makes no attempt to assess the economic value of such improvements to offset the simple cost of the drug. It also makes no attempt to incorporate the financial benefits resulting from continued employment for a patient with a long term disabling condition, the savings from reduced hospital admissions and so on.
- 2.4. The individual's quality of life and the impact of the condition upon normal daily life are extremely important to patients but increasingly become vital for independent living (where many individuals have no close relatives to support them and if they do the 'carer' faces the financial impact of providing care). Patients rate these aspects highly so it is usual that these factors result in an additional emotional and financial burden either to them or their close relatives. The indirect costs in long term conditions are often much higher than the calculated direct costs.
- 2.5. The values relevant to one disease will vary from disease area to disease area. So if pain is the most significant and debilitating factor then this may have to be considered with the parameters that are most likely to be effective (e.g. mood, sleep, social participation, work). However if it is improvement in vision, again these aspects will need to be defined differently. It is probably appropriate that in the scoping a clearer analysis of the key aspects that have affected that disease over time should be more effectively scoped and considered. It is also how heavily these should be weighted against RCT evidence that usually considers safety in the first instance.
- 2.6. Some therapeutic options may give a patient more freedom or reassurance (for example some patients may benefit from a more expensive subcutaneous therapy where another would benefit from a treatment that resulted in a monthly morning in hospital to receive an infusion). These benefits may relate to work or family issues or in some circumstances anxieties about support and additional health needs. Yet some appraisals fail to adequately consider these issues.
- 2.7. A more tailored approach should be considered when scoping the specific disease area. This scoping should consider potential benefits to the society and the health economy in the context of the specific condition or intervention. The ethical principle of justice requires that we treat people equally in so far as they are equal and unequally in so far as they are unequal.
- 2.8. The present approach to assessing the value of a treatment makes no such allowances for relevant differences between diseases and between individual patients' perspectives but represents a "one size fits all" approach.

3. What is the relationship between innovation and value?

- 3.1. Innovation, if properly encouraged and managed, has value – to the wider research community, to encourage future research but also to build upon the knowledge of the disease in question.

- 3.2. Almost inevitably the value of an innovation will be known only in retrospect, when sufficient experience has been gained to understand a treatment's effectiveness, rather than just its efficacy. Additional value, through advances in understanding of pathology and natural history, or through unexpected gains in other areas, is necessarily unpredictable. Confining decisions about funding innovative treatments to simplistic assessments of QALYs based primarily on evidence of efficacy risks losing much that is valuable.
- 3.3. One very practical way of valuing innovation would be to provide conditional or time limited approval of new technologies or therapies in order to allow an experiential evidence base to build from the perspective of the clinician and the patient. A carefully constructed framework could be put in place (similar to those used in research trials) which would facilitate the deliberate collection of real time data to inform decision making at the end of the trial period.
- 3.4. Innovation and value are interlinked and complement each other. Innovation often has value and the quest for better value may lead/result to innovation in improving patient's outcome. Overall, the RCN believes that it would be important for NICE to adopt a range of flexibilities and perspectives in valuing innovation so as to broaden both our understanding of the concept of value (beyond current financial models) and in order to seek greater engagement from the public in a necessary discussion about what can and cannot or should and should not be provided by the NHS.

**RCN Rheumatology Forum
RCN Ethics Forum
RCN Policy Unit**

March 2009