

ABHI Response to the Kennedy short study on <i>Valuing Innovation</i>
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Introduction

1. The Association of British Healthcare Industries (ABHI) is the industry association for the UK medical technology sector. Our membership is made up of companies that innovate, develop and manufacture the medical technology and devices essential for the NHS.
2. The medical technology industry is made up of over 2,000 companies, over 80% of which are small and medium sized companies. The industry employs around 50,000 people, and provides an export surplus for the UK economy. The healthcare devices and diagnostics industries comprise a series of sub-sectors loosely grouped around product types and technologies. The size of the UK market exceeds £8bn p.a. (BERR figures for 2006, website accessed 3/4/09: <http://www.berr.gov.uk/whatwedo/sectors/biotech/healthtech/metrics/page46980.html>)

Executive Summary

3. ABHI welcomes the opportunity to participate to this consultation and the very useful input it will bring to the definition of the '*Single Evaluation Pathway*' for innovative technologies. (reference: High Quality Care for All: para 51)
4. This research into value and innovation is particularly critical for medical devices as the current 'evaluation landscape' is more favourable and more adapted to pharmaceutical innovations.
5. In its first 10 years NICE has appraised considerably more pharmaceutical products than other medical technologies.
6. Given the importance of NICE as a gateway to the NHS, this puts medical technology at a disadvantage to pharmaceuticals in gaining access, to the potential detriment of the NHS.
7. For ABHI purposes, it is important to highlight the differences between medical devices and pharmaceuticals in terms of:
 - a. Much shorter product development
 - b. Shorter product lifecycles
 - c. Much faster development of similar products

- d. Medical devices frequently involve a change in the organisation of care, patient pathways which in turn can provide much higher benefits for health care system efficiency

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

8. HTA processes being developed must seek to be pragmatic, inclusive, transparent, and timely

9. **Pragmatic** - NICE evaluations should include appropriate methods for the evaluation of devices. The reliance of the NICE Reference Case on Randomised Controlled Trials (RCTs) is too rigid for medical devices as blinding is difficult to ensure, clinical responses are particularly susceptible to inter-patient variation and the 'learning curve' and variation in technical proficiency affect outcome.

In the case of NICE Technology Appraisals, the points above support the development of a device-specific Reference Case. Either on its own or as appendix to the Methods Guide, it would address differences in evaluation for devices due to issues such as learning curve, incremental improvement, competitive markets, inappropriateness of RCTs in some instances, and the fact that new technologies usually require organizational and pathway changes to generate cost-savings.

10. The current analysis only looks at benefits to patients (clinical effectiveness) and benefits to the NHS (cost-effectiveness). Wider benefits to carers, wider societal benefits (ability to go back to work, savings in other Government departments), improved efficiency of delivery of care should be included.
11. NICE Reference case currently uses cost/QALY as the sole measure of value. Flexibility should be applied to this threshold to take into account the innovative nature of a technology and the wider benefits it provides.
12. Maybe more importantly appraisals of innovative products should take into account their importance in supporting wider NHS priorities such as 18 weeks, 'duty to innovate', bringing care 'closer to home' – rather than a product in isolation.

13. **Inclusive and transparent** - NICE needs to ensure **transparency** and **stakeholder engagement** at all stages so that the innovative nature of a technology is clearly understood and communicated.
14. The perspective of the manufacturer is critical in the evaluation of an innovation, and engagement is not consistent between the range of NICE evaluations (technology appraisals, clinical guidelines, interventional procedures).
15. **Timely - too early evaluation could be misleading:** Medical technologies continually update with iterative improvements based on new science, technology and materials, their use is to a large extent governed by the ability of the healthcare provider to use them effectively and integrate them into healthcare practices.

Therefore defining innovation in health technologies provides a challenge and treating it in a bipolar way (either innovative or not) ignores much of the rationale for development of future products.

Medical devices are often fast-changing technologies. Their development is characterised by a constant flow of incremental product improvements. Accordingly, the life cycle of a specific type or variation of a device is often as short as 18 – 24 months, which is considerably less than that of pharmaceuticals. Too early an assessment of value in an innovative technology might ignore both the learning curve phenomenon and the fact that the process of innovation in medical devices is one of continuous, often incremental improvements in close iteration with the users of the technology.

16. The effectiveness of an innovative device as part of a medical procedure depends to a large degree on the user's experience with the device and procedure in question. Innovative technologies are not always straightforward and quality in performance requires training and/or frequent repetitions over time. This is the so called "learning curve" phenomenon.
17. Learning curves may affect the outcomes of procedures associated with many innovative devices, especially immediately after market introduction. This poses a question on the timing of the assessment of value in medical devices. Too early an assessment could result in a decision to restrict access to a potentially valuable technology and subsequently limit further innovation as a result of the learning curve phenomenon. While a later more timely assessment could be highly beneficial in informing the process. The timing of the measurement of the value in innovation should be done on a case by case basis in collaboration with the appropriate stakeholders including industry.

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

18. Value is the pragmatic balance between the cost of technological innovation and the benefits that accrue.
19. Because of the variations between devices, diagnostics, and drugs, a single hierarchical categorization of value will not capture the appropriate value weights for each technology.
20. Paraphrasing a known idiom, '*value is in the eye of the beholder.*' Different perspectives will weigh attributes of value differently. Processes built on transparency and appropriate stakeholder involvement can ensure that all appropriate values are taken into consideration and weighed appropriately.
21. Therefore, it is recommended to include a process, for example in the scoping phase, which defines the value weights for the technology. The process will solicit input from stakeholders (including for example the Citizens Council); a pursuant discussion between the NHS and stakeholders will lead to consensus on weighting; and the appraisal will incorporate the values and weighting as defined.
22. The result is an evaluation that adequately considers value of innovation beyond the QALY, potentially capturing patient outcomes in the context of societal impacts and patient experience while ensuring Quality and Ethics considerations are reflected.
23. It is crucial that the different attributes of value are recognized early in the NICE processes. An exercise at the topic selection phase, for example, will create a need-based priority list that is driven by a wider range of benefits & beneficiaries than currently exists.

How should innovation in health technologies be defined?

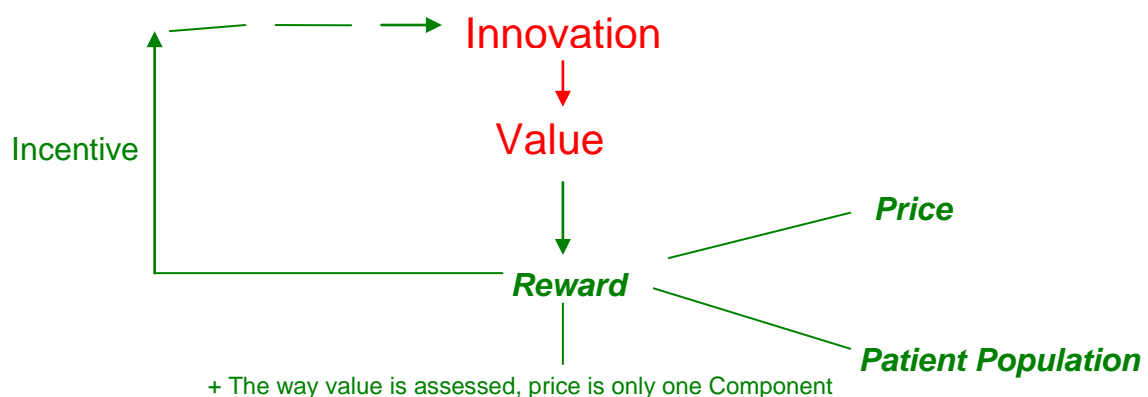
24. Innovation is defined as a measurable or perceived benefit (value).
25. An innovation is a technology or approach that potentially delivers a value proposition to patients, carers, clinicians, standards of care and/or the health system. There may be a single or multiple beneficiaries.
26. Whether a new surgical technique, a new systems approach to a health issue or a product, an innovation: often satisfies a clinical need, provides benefit to the patient (clinical or quality of life), and/or changes the standard of care to

improve outcomes or efficiency. Other benefits may accrue and should be introduced by relevant stakeholders (Question 2 above).

27. The benefit (value) may be measured through efficiency gains, quality of life impact, clinical outcomes, and/or societal impact. The weighting of multiple measures is a decision that must be made early in the process (Question 2 above).
28. Innovations are those that have a direct impact upon introduction but may also include those technologies that have evolved over a period of incremental improvements. Both types of innovation should be considered equally.

What is the relationship between innovation and value?

29. We believe the relationship between innovation and value is a continuous one and is demonstrated by the diagram below. The way in which the value produced through innovation is assessed has a critical role in incentivising further innovation. Breaking this down, the perspective taken on value in the evaluation process, the combined role of the price charged and the size of the recommended patient population will all determine whether it is worth investing in further research of this type. This highlights the critical role of the definition of value in terms of defining the types of innovation that are likely in the future and hence the standards of care available to the NHS. As such the framework taken on value should be fully aligned to the future objectives of the NHS, so the drive for 'quality' in its many and varied forms need to be taken into account.



Conclusion

30. Finally, in its impressive growth phase there has occasionally been the view that NICE perceives innovation as a burden. The implication is that extra resources and expertise are required to perform assessments and to understand the value and impact. Through this consultation and project, NICE has the opportunity to embrace innovation and the value medical technology brings to wider NHS.