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When should NICE restrict access to new drugs until more research has been undertaken?

A new decision framework to support NICE recommendations on the use of new drugs and devices in the NHS is published today by the Centre for Health Economics at the University of York.

NICE (National Institute for Health and Clinical Excellence) is increasingly making 'fast-track' recommendations to the NHS on the use of new drugs or devices soon after these products are first licensed.

Often these decisions are being made when the evidence base to support these technologies is limited. There may be substantial uncertainty surrounding overall effectiveness, the patients most likely to benefit, the potential for harms and whether they actually represent best use of resources for the NHS.

An underused option available to NICE is to make an 'only in research' recommendation; where a drug or device can only be used in the context of an appropriately designed programme of evidence development. Having further evidence can be valuable but guidance on how best to balance the benefits of access to a new drug or technology with the value of further evidence about its performance has been lacking.

Researchers from the Universities of York and Brunel have been working to develop a transparent, consistent and methodologically robust approach to formalise a process NICE can use to produce its 'only in research' recommendations.

Project lead, Professor Karl Claxton from CHE said:

"Uncertainties about treatment effects can never be entirely eliminated but they can be reduced by further evidence. This in turn facilitates better decisions on patient outcomes and on best use of finite resources in the NHS, which are crucial at a time of financial constraint.

"Our research has established the key principles of what assessments are needed, as well as outlining how these assessments should be made. Our framework will enable NICE to make 'only in research' recommendations in an explicit and transparent manner."

The project is funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme.

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Notes to Editors

1. The National Institute for Health Research Health Technology Assessment (NIHR HTA) programme commissions research about the effectiveness, costs, and broader impact of health technologies for those who use, manage and provide care in the NHS. It is the largest NIHR programme and publishes the results of its research in the Health Technology Assessment journal, with over 550 issues published to date. The journal's 2010 Impact Factor (4.197) ranked it in the top 10% of medical and health-related journals. All issues are available for download free of charge from the website, www.hta.ac.uk.
2. The National Institute for Health Research provides the framework through which the research staff and research infrastructure of the NHS in England is positioned, maintained and managed as a national research facility. The NIHR provides the NHS with the support and infrastructure it needs to conduct first-class research funded by the Government and its partners alongside high-quality patient care, education and training. Its aim is to support outstanding individuals (both leaders and collaborators), working in world class facilities (both NHS and university), conducting leading edge research focused on the needs of patients. www.nihr.ac.uk
3. Karl Claxton, Steve Palmer, Louise Longworth, Laura Bojke, Susan Griffin, Claire McKenna, Marta Soares, Eldon Spackman and Ji-Hee Youn. *Uncertainty, evidence and irrecoverable costs: Informing approval, pricing and research decisions for health technologies*. CHE Research Paper 69 York: University of York, 2011. www.york.ac.uk/che/publications/in-house
4. This report presents independent research commissioned by the Medical Research Council and the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme (project number 06/90/99) and will be published in full in Health Technology Assessment. The views and opinions expressed are also those of the authors and do not necessarily reflect those of the MRC, NIHR, NICE, NHS or the Department of Health.
5. The Centre for Health Economics is a research department at the University of York. The Centre's aim is to undertake high quality research that is capable of influencing health policy decisions. The Centre is one of the largest health economics research units in the world. www.york.ac.uk/inst/che/