The luck of being late

(Should international health care policy makers follow the NICE model?)

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Over the past fifteen years, health technology assessments (HTAs) including economic evaluation have become a standard method to inform pricing and reimbursement decisions, in particular for new pharmaceuticals[1]. Britain's highly acclaimed National Institute for Health and Clinical Excellence (NICE) features prominently among the international HTA initiatives that followed the early examples of Australia and Canada[2]. NICE has been described as representing "the closest anyone has yet come to fulfilling the economist's dream of how priority-setting in health care should be conducted"[3]. It has been further asserted that "NICE tends to concentrate on the difficult choices, where there are usually trade-offs between increased benefit and increased costs", representing "these situations where economic analysis is likely to have the greatest added value, including the quantification of the uncertainty surrounding the decision"[4]. A review team of the World Health Organization (WHO) commissioned by NICE to appraise the methods and processes of its technology appraisal program "was impressed by the commitment to using rigorous methodology throughout the process of technology assessment"[5]. Leading representatives of NICE have recommended the Institute's approach as a role model for other jurisdictions, claiming "the conditions […] seem ripe for a NICE in the United States"[6] and praising its use of cost-effectiveness analysis as "an exemplar of a deliberative process"[7].

This has not been without effect. Debate in countries such as France, Germany and the United States – all three late followers with regard to the formal adoption of health economic evaluations as an integral part of HTAs – includes consideration of the British experience. A

new in-depth analysis of the NICE standard process for multiple technology appraisals (MTAs) indicates that the NICE approach may not be as robust as expected when addressing complex clinical decision problems[8-10], suggesting potential problems pertaining to

(a) the integration of clinical and economic perspectives, as NICE allowed two very different streams of work to evolve (technology appraisal and clinical guideline development);

(b) the high level of standardization of NICE evaluation processes, requiring to make clinical problems fit to a predetermined "one size fits all" solution strategy, including over-reliance on quality-adjusted life years (QALYs) as a universal and comprehensive measure of benefit, which in some cases may stand in the way of using the best available clinical evidence;

(c) the apparent absence of an effective quality assurance system for HTAs, with the possible consequence of a limited technical quality of some assessments;

and (d), somewhat surprisingly, the appraisal process itself, which does not fulfill the criteria of 'accountability for reasonableness' as espoused by NICE[11-14], especially (but not limited to) transparency problems regarding economic models and the codification of decision criteria other than cost-effectiveness.

Despite the accomplishments of NICE in many areas, notably including its pioneering role in the advancement of certain methods such as mixed treatment comparison techniques and probabilistic sensitivity analyses, international health care policy makers may prefer learning from NICE (and the experience in other countries such as Australia and Canada) instead of copying it. This will almost certainly include careful consideration of the social value judgments by NICE, which they may or may not share. It will be interesting to watch the

currently ongoing integration of health economic evaluations into the HTA process by the Haute Autorité de Santé (HAS) in France and by the Institute for Quality and Efficiency in Health Care (IQWiG) in Germany. This is promising to tell tales about the good or bad luck of being late.

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