ON THE VALUE OF LOWER LEVEL EVIDENCE OF EFFECTIVENESS IN REIMBURSEMENT DECISIONS: A DECISION ALGORITHM TO GUIDE POLICY MAKERS
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OBJECTIVES: Reimbursement decisions require evidence of effectiveness and a randomised controlled trial (RCT) is seen as the best study design to demonstrate effectiveness. However, there may be situations where a double-blind RCT will not be considered necessary, appropriate, methodologically feasible, or ethical. The aim of this study was to develop a decision algorithm to determine the appropriate level of evidence when assessing the effectiveness of a medical intervention.

METHODS: The initial algorithm was based on the literature and interviews with personnel at the Health Care Insurance Board (CVZ), the central reimbursement authority in the Netherlands. In addition to the results of a previous study of 72 reimbursement decisions concerning medical specialist care, we also retrospectively studied 20 reimbursement decisions made by CVZ to identify any arguments why lower level evidence could be accepted. We then interviewed several Dutch and foreign experts. Our algorithm was continuously refined during the study and prospectively validated using new reimbursement decisions.

RESULTS: RCT evidence was lacking in most positive reimbursement decisions (8/9), but also in most negative reimbursement decisions. Methodological issues can play a role in accepting lower levels of evidence, e.g. when blinding is impossible. Moreover, an RCT may be unsuitable (e.g. due to time constraints) or viewed as unnecessary (e.g. in testing paracetamol). Finally, ethical reasons can play a role in accepting lower level evidence. Our decision algorithm contains a stepwise approach to determine the appropriate level of evidence, which includes (double-blind) RCTs, observational comparative effectiveness research or non-comparative effectiveness research.

CONCLUSIONS: Policy regarding acceptance of lower level evidence in reimbursement decisions needs to be transparent. Our decision algorithm can guide decision makers in reaching a structured and well-founded decision as to whether lower level evidence of effectiveness is appropriate.

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CLINICAL TRIAL ACTIVITY IN GREECE: OPPORTUNITIES MISSED, SOON TO BE FORGONE?
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OBJECTIVES: Clinical trials (CTs) represent important investments in the clinico-economic setting, as well as in the “human capital” of developed economies. The purpose of the study was to depict CT activity in Greece for 2010. A questionnaire-based survey was conducted among the members of the Hellenic Society of Pharmaceutical Economics and Outcomes Research (SFEE). Each company was requested to return via email one questionnaire per interventional CT approved by the Hellenic National Ethics Committee in the year 2010. Items in the questionnaire focused on the following points: phase of the trial, duration, number of patients, CT sites, therapeutic area of the agent under survey and planned budget for the study. The survey lasted for 4 months (December 2010-March 2011).

RESULTS: Fifty of the 65 SFEE members returned questionnaires (response rate 77%). The majority of CTs was phase-III trials (67%), mainly on oncology (26.3%), endocrine disorders (16.4%) and cardiovascular diseases (13.9%). Most CT sites were affiliated with a university (46%) or an NHS hospital (46%), enrolling 4.5-7.5 patients, on average, depending on CT phase. The average budget per CT was 296,600€ (s.d. : 389,948€). In total, 120 interventional CTs were approved in 2010 in Greece, with the total investment estimated at 6.6 million Euro. CONCLUSIONS: Compared to its European peers, the number of CTs conducted in Greece is extremely low. Within a global market context, this constitutes a problem of lost research opportunities and underuse of the country’s acknowledged scientific capacity. Major hurdles could be identified in the “bureaucracy” and complexity of the approval process, mainly within NHS, lack of acknowledgement of CT as key priority for research investment and lack of a strong framework for health technology assessment. Quick changes are necessary, in order to cover the distance lost.

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PUBLIC HEALTH AND PREVENTION IN EUROPE: IS IT COST-EFFECTIVE?
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OBJECTIVES: In the public debate surrounding public health and prevention, it is sometimes assumed that preventive interventions are by definition cost-effective. This study aims to explore whether preventive pharmaceutical interventions are more cost-effective than a curative approach to diseases. METHODS: A descriptive study identified European economic evaluations in the Tufts Medical Center Cost-