METHODS & CONCEPTS

TRANSFERABILITY OF ECONOMIC EVALUATIONS: CAN RESULTS FROM ONE GEOGRAPHIC AREA BE USED TO HELP INFORM HEALTH CARE DECISION MAKING IN ANOTHER?

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There has been increasing pressure to consider using published economic evaluations or health technology assessments from other jurisdictions for local reimbursement decisions. Geographic transferability has the potential to facilitate assessments that would otherwise be infeasible and the potential to make more efficient use of global evaluation resources. OBJECTIVES: To review and summarize the literature on: 1) factors affecting geographic transferability of economic evaluation evidence; 2) criteria, guidelines or decision rules for determining transferability potential; and 3) approaches which have either been proposed or used in practice for transferability. METHODS: A systematic literature review on transferability was conducted. Electronic databases, hand searching and bibliographic searching techniques were utilized. Two classification systems were developed; one summarizing transferability factors, and another summarizing transferability approaches. RESULTS: Titles and abstracts of nearly 5000 articles were reviewed and 808 in full text. There was a substantial literature identifying over 70 factors potentially affecting transferability. From these papers we developed a classification system which grouped these factors into five broad categories based on characteristics of the patient, the disease, the provider, the healthcare system and methodological conventions. Only three papers were identified that proposed criteria, guidelines or decision rules for determining transferability potential and 38 empirical studies attempted to transfer economic evaluation data from one country to another. CONCLUSIONS: There is strong evidence indicating that transferability of economic evaluation data is complex and can result in misleading results. The subjective nature of the proposed systems for determining transferability potential highlights the need for additional research. Approaches which have been used for transferability suggest that there is a need for country-specific substitution of practice patterns data as well as unit cost data. The results from this review will assist researchers and government decision making bodies when considering and conducting transferability studies.

HEALTH CONDITIONS IN POSTMENOPAUSAL WOMEN AND IMPLICATIONS FOR THE DESIGN OF CLINICAL TRIALS OF AROMATASE INHIBITORS

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OBJECTIVES: To establish reference levels within the US population of postmenopausal women for conditions often evaluated in clinical trials of aromatase inhibitors for the treatment of breast cancer. METHODS: The prevalence of selected health conditions was estimated using the 2002 Medical Conditions file from the Medical Expenditure Panel Survey (MEPS). The study cohort included women 55 to 85 years of age, without cancer or cancer related activity, and without hormone replacement therapy in 2002. Conditions of interest included osteoporosis, fractures, joint related problems, and lipid disorders. Estimated prevalence rates from MEPS were compared with those reported in clinical trials of AIs identified from Medline and other sources. RESULTS: A total of 2723 MEPS survey respondents representing 20.4 million US women aged 55 to 85 years were included in the prevalence estimation sample. The most prevalent condition of interest was joint-related problems other than rheumatoid arthritis and osteoarthritis (34.1%, SE = 0.9%); 22.7% (SE = 1.1%) reported dyslipidemia; 10.3% (SE = 0.8%) reported osteoporosis, and 6.0% (SE = 0.6) reported fractures. CONCLUSIONS: The results of this study suggest that conditions evaluated in clinical trials of aromatase inhibitors are commonly found within the US population of postmenopausal women. Moving forward it will be important to collect baseline information on the presence of these conditions in women with breast cancer enrolled in clinical studies of AIs in order to correctly interpret the potential impact of this treatment on these conditions.
commonly prescribed diagnostic tests and to know its effect on their prescribing preferences. METHODS: This study is a descriptive cross-sectional survey which includes data gathering through questionnaire, retrieval, tabulating, and interpreting of results a probability stratified random sampling of 125 TMC physicians (regular consultants, fellows, and residents) was done. The sample size was computed using the Lynche formula. The physicians were stratified by specialties which include Internal Medicine, Surgery, Pediatrics, Obstetrics and Gynecology, Ophthalmology, and ENT-Head and Neck Surgery and were asked to answer a pre-tested questionnaire. Non-respondents were sent another questionnaire for them to answer to increase response rate. The collected data were analyzed using the percentage and weighted average and one-way analysis of variance. Inferential analysis was done using ANOVA. SPSS software was used for these purposes. RESULTS: Verbal interpretation of the descriptive statistics shows that all respondent physicians agree to the statement that the prices of medications and diagnostic tests are important factors which influence them in their practice. Furthermore, the respondent physicians believe that physicians should know the prices of medications and tests they prescribe or order. They also consider the economic status of their patients in their practice. However, descriptive data based on the mean price estimates from all specialties, whether residents, fellows, or consultants, show significant difference in the physician perceived prices of commonly prescribed and ordered medications and diagnostic tests and the actual TMC prices of such medications and tests (p value >0.05) thereby rejecting the null hypothesis saying otherwise. CONCLUSION: The Medical City physician is not aware of the prices of medications and diagnostic tests he commonly prescribes or orders.

**PMC5**

**ARE NON-INFERIORITY TRIALS SUITABLE FOR ECONOMIC EVALUATION? ESTIMATION IS STILL MORE IMPORTANT THAN HYPOTHESIS TESTING**

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OBJECTIVES: The use of cost-minimisation analysis, based on a negative result from a clinical trial, has recently been questioned. Instead, it has been argued that cost-minimisation analysis should only be undertaken as part of an equivalence trial, designed to confirm the absence of a meaningful difference between treatments. The “non-inferiority” trial is becoming a popular method of comparing a new treatment to an existing standard as non-inferiority may be an acceptable outcome for licensing purposes. Non-inferiority trials are designed to show that a new treatment is no less effective than an existing treatment—in reality, it may be more effective or have a similar effect (within a margin of clinical equivalence). METHODS: In this paper, the role of the non-inferiority trial design is critically appraised as a vehicle for economic evaluation. RESULTS: A number of issues are noted in relation to non-inferiority designs that limit their usefulness for making judgements concerning the value for money of treatments. The margin of clinical equivalence is essentially arbitrary and is rendered meaningless once costs (both in terms of resources and the health effects of any adverse events) are considered. From an economic perspective, acceptance of a new treatment can only be recommended if the new treatment is both “non-inferior” in both clinical and cost terms, however, the role of the margin of clinical equivalence (and potentially a similar margin of cost equivalence) serves to cloud the comparison with the traditional concept of “dominance” in economic studies. CONCLUSION: The design of trial in terms of “superiority” or “non-inferiority” does not change the fact that separate and sequential tests of hypothesis for costs and effects independently are to be avoided in economic evaluation. The recommendation remains that estimation and not hypothesis testing should be the key to interpreting cost-effectiveness studies of new treatments.