CATEGORISING RESEARCH: WHERE IS THE FOCUS?

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OBJECTIVES: The quantity of research generated is increasing yearly. It is of interest to determine the types of research being published to assess the content of the current knowledge base. Research can be categorized as randomized controlled trials (RCTs), observational studies (OS), systematic reviews (SR), or economic studies (ES). Our aim was to determine the proportion of research being conducted in these categories and to assess the relative proportions of each across time. METHODS: A citation search was conducted in Medline on 18 June 2008. Search filters for RCTs, OS, SR, and ES were implemented to provide an estimate of research conducted in these categories for the years 1950–2007. The prevalence of each type of research was calculated and changes over time were analysed using logistic regressions. RESULTS: The total probable citations retrieved were: 740,599 for RCTs, 1,217,246 for OS, 1,287,915 for SR, and 325,625 for ES. The proportion of research conducted for each of these overall was 20.7%, 34.1%, 36.1%, and 9.1%, respectively. From 1977 to 2007 there was a 12-fold increase in probable RCTs, a 15-fold increase in both probable OS and SR, and a 9-fold increase in probable ES. Logistic regression analysis showed a significant association between category and time (p < 0.0005). CONCLUSIONS: The majority of research being conducted appears to be focused on OS or reviews of the literature. In contrast, probable RCTs and ES, which are arguably the most useful and rigorous forms of research, together consist of less than one third of the research being conducted. Furthermore, the increase in this research during the previous 30 years is lower than that of OS and SR. It is possible that the focus on SR reflects the growing recognition of the importance of this literature searching technique.
four with a significant increase in ARP, and two with a significant increase in OPC (p < 0.05). By comparison, Medicare Part D resulted in significant TRx increases for ten drugs (and no decreases), eight showed ARP increases and two had ARP decreases (p < 0.05). Interestingly, seen drugs decreased OPC while two increased (p < 0.05). CONCLUSIONS: NICE HTAs had mild effects on the prescription utilization and costs in the US, while Medicare Part D caused fundamental changes to the market parameters measured. The influence of NICE decisions on the US market should be monitored as HTAs are expected to play a more significant role in the advent of Medicare Part D Reimbursement.

HEALTH CARE USE & POLICY STUDIES—Health Technology Assessment Programs

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ANALYSIS OF FACTORS ASSOCIATED WITH REIMBURSEMENT DECISION MAKING IN HEALTH TECHNOLOGY ASSESSMENT AGENCIES (HTA)
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OBJECTIVES: Health technology assessment is used to inform reimbursement decisions for pharmaceuticals in many countries. The political and administrative contexts in which HTA is used vary considerably between countries, as do the decisions on individual products. The aim of this study was to investigate the influence of HTA and other factors on reimbursement decisions.

METHODS: A systematic search was conducted to obtain the documentation for reimbursement decisions on cancer and cardiovascular medicines. Where insufficient information was published, or reports were not available in English, decisions were excluded. The analysis was conducted using discrete response models and included methods of assessment, evidence included and stakeholder involvement.

RESULTS: Detailed information was obtained on 194 decisions from Australia, Belgium, Canada, England, France, Scotland and Sweden. The pooled analysis showed that 27% of medicines were recommended, 41% were recommended for restricted use and 32% were not recommended. The multinomial logistic regression showed that the number of RCTs, disease area, use of sensitivity analysis and public interest had a statistically significant impact upon decisions. The use of cost-utility analysis in the supporting HTA was found to reduce the probability of a positive recommendation. The analysis for those countries that included cost-utility analysis showed that the value of the ICER had a statistically insignificant impact upon the decision. However, a sub-analysis for decisions in England showed that this was not found to be statistically significant.

CONCLUSIONS: These findings may reflect varying approaches to conducting economic analysis, differences in cost-effectiveness thresholds and variation in the weight given to economic evidence in informing decisions within countries. The individual product level factors explain some of the variation in reimbursement decisions across countries. Further variation may be explained by the health system and policy context in which decisions are made. The next stage of the work will investigate these factors directly.

PHP50
UNIVERSAL STEPS IN PERFORMING EARLY-STAGE MEDICAL TECHNOLOGY ASSESSMENT
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OBJECTIVES: Early-stage medical technology assessment (MTA) is sometimes conducted in an ad-hoc manner, if it is performed at all. Identification of universal steps in early-stage MTA would catalyze the development of valuable technology.

METHODS: Universal steps in early-stage MTA were developed following evaluation of a new stroke rehabilitation strategy targeting the urban Chinese population. Literature review, physician and patient interviews, and decision modelling were performed to appraise current stroke care and evaluate methods to improve it. Different rehabilitation strategies were recognised and described, and their costs and health effects were estimated and compared.

RESULTS: Certain universal steps in early-stage MTA could be identified. An important first step is the creation of a detailed study plan that includes evaluation criteria and may also discuss the value of a disease progression model. A second step consists of qualitative and quantitative descriptions of current treatments and new technologies. This step focuses not simply on acquiring quantitative estimates of costs, health effects and quality of care, but also on identifying areas for quality improvement. Since the literature review did not yield sufficient information, other methods (i.e., interviews) were needed to ascertain attitudes regarding usual care and behaviour. These methods provided extra insight into physician and patient preferences, insight that was used to modify the evaluation criteria. Subsequently, the new technology was described both qualitatively and quantitatively. Lastly, the costs and health effects of the treatments were compared using standard techniques (e.g., uncertainty analysis). These results identified where more information needed to be collected.

CONCLUSIONS: As with later-stage MTA, there is a need and an opportunity to develop universal steps for conducting early-stage MTA. They supplement, but do not replace, the steps and techniques applied during later-stage assessments. If properly formulated, they can be used to facilitate good internal decision-making during the development phase.

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OTHER HEALTH TECHNOLOGY ASSESSMENT GROUPS OPERATING IN ENGLAND; ITS NOT JUST NICE THAT NEEDS TO BE TAKEN INTO CONSIDERATION
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OBJECTIVES: In England only new innovative technologies evaluated useful and cost effective are taken up by health care providers. NICE leads the way for this managed entry, but delays in publication of guidance, and the fact it only covers technologies with the potential to have large financial impact, leaves local payers looking to other technology appraisal groups for guidance—often local groups, to review a technology in line with local needs, demographics and priorities. There are more than 30 of these review groups operating in England, on either a national or local level which influence prescribing, funding, and commissioning decisions. This research was undertaken to understand, and map the influence of these organizations.

METHODS: A total of 65 senior managers from SHAs, PCTs, hospital Trusts, and HTA organisations were interviewed, using qualitative and quantitative measures, to provide an indication of the current, and future influence of HTA organizations in England.

RESULTS: For interventions without forthcoming NICE guidance, NHS organizations are responsible for accessing publicly available evidence to determine local policies for managed entry. Notification of new drugs is generally from one of the national information portals. In the absence of NICE guidance, the SMC is, for most, the next port of call. If there is no NICE, or SMC guidance, HCPs generally look to their regional group, or the HTA group with relevant therapy experience. The remit, focus and influence of the different regional groups was assessed and found to vary.

CONCLUSIONS: Because of delays in NICE guidance of up to...