Q3

Does Cost-Effectiveness Analysis Discriminate Against Patients with Shorter Life Expectancy?

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OBJECTIVES: The UK’s National Institute for Health and Clinical Excellence (NICE) has been accused of discriminating against patients with shorter life expectancy by embracing the use of quality-adjusted life years (QALYs) within cost-effectiveness analysis (CEA). The basis of this claim is that patients with shorter life expectancy have fewer QALYs to gain from treatment and so NICE’s guidance inherently discriminates against such patients. Such criticisms may also be directed at similar decision making agencies. Our objective was to formally identify the circumstances under which CEA-based decision making discriminates on the basis of life expectancy.

METHODS: We developed a simple model of a CEA-based decision making process in which a technology is considered cost-effective for a particular patient cohort only if the ICER for that cohort lies below a fixed cost-effectiveness threshold. For such decision making to discriminate on the basis of life expectancy, the ICERs for two hypothetical cohorts of patients – identical in all ways except life expectancy – must lie on either side of the threshold.

RESULTS: We find that CEA does not inherently discriminate on the basis of life expectancy but that scope for discrimination arises in the case of specific technologies having identifiable characteristics. Such discrimination may in fact favour those patients with shorter life expectancy in all cases. The only case of discrimination shown is where the likelihood of discrimination on the basis of life expectancy – this is particularly relevant in light of the recent discussion around NICE’s discounting practices. CONCLUSIONS: It is recommended that agencies such as NICE consider the possibility of discrimination arising from their use of CEA. Accusations of inherent discrimination, however, appear to be misplaced. It is argued that these claims are founded upon a fundamental misunderstanding of the role of QALYs in CEA, particularly within the decision rules adopted by policy makers.

Q4A

Is the Aim of the Healthcare System to Maximize QALYS? An Investigation of ‘What Else Matters’ in the NHS

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OBJECTIVES: It is often assumed that the objective of health care is solely to maximise health using available resources. This is the principle underpinning NICE’s use of cost-effectiveness analysis based on incremental cost per QALY gained. Yet research has shown that local decision-making processes show that cost per QALY is far from the only consideration. Similarly, many national NHS policy initiatives are driven primarily not by QALY gain, but by ‘process-of-care’ and other considerations. The DH is required to undertake and publish Impact Assessments (IAs) identifying the costs and benefits expected from all new policy implementation. We analyse all IAs carried out in 2008-2009 to identify the benefits considered by the DH as relevant to its decision making.

METHODS: The stated benefits of each policy were extracted from the relevant IA. A combination of methods was used to categorise these.

RESULTS: 51 IAs were analysed, 8 of which mentioned QALY gains as a benefit. 162 benefits other than QALY gains were identified. Apart from improving health outcomes, common types of benefit included reducing costs, improving quality of care, and enhancing patient experience and empowerment.

CONCLUSIONS: Many of the policies reviewed were identified on the basis of benefits unrelated to health outcomes, and being used to apply a monetary valuation to QALY gains (in IA cost-benefit calculations) are not consistent across IAs, or with NICE’s stated threshold range. We consider the implications for NHS decision making and NICE guidance, and the meaning of allocative efficiency in the NHS.

POSTER SESSION I: HEALTH CARE USE & POLICY STUDIES

Health Care Use & Policy Studies – Consumer Role in Health Care

PHP1

Use of Structural Equation Modeling to Explain Consumer Behavior Towards Generic Drug Discount Programs

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OBJECTIVES: The study attempts to assess the robustness of constructs with the Theory of Planned Behavior (TPB) in explaining intention to use generic drug discount programs (GDDPs). METHODS: A self-administered questionnaire was distributed to consumers filling a prescription at pharmacies in Houston (Texas, USA) that carried generic discounts. Demographic, TPB constructs (including TPB constructs), and GDDPs availability and usage were measured on the patients' most recent prescription medication use in two parts: a listing of current medications (location of filling, price paid, brand/generic, discount program use) and inquiries on program use, if applicable, as well as patient demographics. RESULTS: The overall convenience sample over the two cohorts included 414 individuals, 203 in 2008 and 211 in 2010. The sample was mostly Caucasian (78.7%), most patients had prescription drug insurance coverage (92.1%), and a large majority of medications filled were for chronic use (84.3%). Patient demographics between the two populations were similar for all characteristics with one exception: a higher number of respondents in the 2010 cohort (2.5 vs. 1.4, t(4.2) = -1.11, p = 0.001, and 29.9% of those surveyed in 2010 had used a discount medication program versus 5.4% in 2008 (X^2 = 42.10, p = 0.001). Factors associated with program use included patient age 50 – 64 years (OR, 3.79; 95% confidence interval [CI], 1.45 – 9.90; p = 0.004), and an annual household income of less than $24000 (OR, 2.64; CI, 1.12 – 6.22; p = 0.02), and the filling of medications for chronic use (OR, 1.86; CI, 1.20 – 2.88; p = 0.005). CONCLUSIONS: Limited differences in patient most likely to use discount prescription medication programs existed in the studied population. More extended analysis of the program utilization is needed to better understand patient use of such services.

PHP3

Federal Enforcement Actions Against Fraud and Abuse by Pharmaceutical Manufacturers: 1996-2010

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OBJECTIVES: To expand on the scope of the limited prior research by reporting on concluded investigations involving pharmaceutical manufacturers independent of whether or not they involved qui tam relators between 1996-2010. METHODS: All cases involved pharmaceutical manufacturers and FCA violations, which impose liability of up to triple damages and civil penalties of $5,500 to $11,000 per claim for submitting false claims to the government. Data were from Department of Justice during 1996-2010. RESULTS: Since 1996, resolution of 31 FCA cases involving pharmaceutical manufacturers accounted for $12 billion in recoveries. Pharmaceuticals cost $8 million between 1996-2000 (one case), $3.9 billion during 2001-2005 (15 cases), and $8.1 billion during 2006-2010 (15 cases). Billing fraud was implicated in 18 cases ($3.7 billion), off-label marketing in 12 cases ($4.4 billion), kickbacks in 5 cases ($2.7 billion), and producing defective pharmaceuticals in one case ($750 million). Qui tam relators initiated 77% of the cases (median reward $31 million). Six settlements included criminal fines. CONCLUSIONS: With expansion of government healthcare, fraud investigations of pharmaceutical manufacturers will undoubtedly continue. These investigations have the potential to reduce costs and improve the quality of pharmaceutical use.

PHP4

When Stakeholders Don’t Agree: Discrepancies in MAB “APPROVALS” OVER THE PAST TEN YEARS

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OBJECTIVES: In the drug development process the priorities of the stakeholders (manufacturers, payers, regulators, patients, physicians) often do not align, and at times are in conflict, e.g. in the US consumers aren’t concerned about cost, but private payers are. With cost as a significant driver to multiple decision makers, we explore monoclonal antibodies (mAbs) as a drug class and the handling of their approvals and authorizations by the US and UK key bodies. METHODS: The following sources were summarized for mAbs approved in the past 10 years: the regulatory approval decision in the United States and the United Kingdom; the payer coverage decision, if applicable and available, relevant patient advocacy groups’ statements; and statements on behalf of medical organizations. Discrepancies between initial regulatory decisions and the statements of the other stakeholders were noted. RESULTS: The stakeholders show the use of clinical data to advocate differing stakeholders’ views. In the case of natalizumab, patient advocacy groups and regulators disagreed on whether the risks outweighed the drug benefits. In judging the value of bevacizumab for breast cancer patients, regulators and payers disagreed at odds. Furthermore, the debate between the payers and the manufacturer on the use of off-label bevacizumab seems to hinge on the clinical results from the US National Eye Institute. CONCLUSIONS: Although physicians continue to play a critical role in determining drug use once a product is approved, other stakeholders (e.g. patients and independent researchers) are increasing their sway
in the market. Given the discrepancies between the decisions of the regulators and the payers, drug manufacturers are obliged to demonstrate a product’s value to patients and payers, as well as to show that it is safe and efficacious to regulators. The incorporation of the payers’ viewpoint in the development process will ease the gap between stakeholders.

%PHPS

INCENTIVE-BASED INTERVENTIONS – REWARDING PATIENTS FOR GOOD BEHAVIOUR
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OBJECTIVES: Incentive-based schemes, in which patients are rewarded for making behaviour changes or reaching treatment goals, are becoming more common in healthcare worldwide. Issues surrounding the cost-effectiveness of behaviour change, as well as the ethical implications of rewarding members of society who exhibit inappropriate behaviours, are some of the issues which must be taken into account when considering these schemes in real-life. The aim of this study was to provide an account of incentive-based schemes currently under investigation, in an effort to determine where the perceived benefits of these schemes may lie for future implementation.

METHODS: A Critical trials gov search was performed to identify trials that specifically tested the use of incentives in encouraging behaviour modification in target populations.

RESULTS: A total of 76 clinical trials, predominantly based in North America, were identified as appropriate for analysis. The most commonly targeted groups included drug dependent individuals, overweight individuals (with exercise or weight-loss programmes) and smokers, implying that these schemes are most commonly used to induce lifestyle changes that promote health. Most trials looked at the clinical-effectiveness of incentives at achieving behaviour change, with minimal emphasis on the cost-effectiveness of adding the incentive. The majority of the trials (43/76, 57%) used monetary or voucher reimbursement systems as the incentive for patient behaviour modification, with 10 additional schemes providing the opportunity to win a prize. Only 1 scheme directly connected healthy behaviour to treatment outcomes and 1 scheme offered treatment for free if the patient sustained compliance for a specified period.

CONCLUSIONS: The scope for the use of incentive-based schemes is broad, with potential applications in numerous different diseases in which good compliance is required; yet those which require lifestyle change. However, further economic analysis of the cost-effectiveness of such schemes is essential before they are implemented more widely.

Health Care Use & Policy Studies – Diagnosis Related Group

%PHP

EXPLORE THE USE OF DRUGS IN MEDICAL INSURANCE BILLING IN CHINA
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OBJECTIVES: With the advancement of the China health care reform and the increasing health care expenditure, it is imperative to explore other billing methods in addition to the existing item-based billing. Since 1980s, US and many other countries have adopted DRGs to manage health care insurance to control health care expenditure and achieved positive outcomes. The objectives of this study are to understand and compare DRGs from other countries in the implementation of DRGs, and make recommendations on how to adopt DRGs in China.

This study started in 2003. It is composed of three phases: phase one is to study how DRGs are implemented in the US, Australia, and Germany; phase two, the core part of this study, is to analyze the grouping method. Based on learnings from US, Australia, and Germany, we randomly collected 70000 patient records taking place between 2002 and 2005 from 12 tier-one Beijing hospitals, developed a theoretical DRGs grouping model, and completed over 600 DRGs automated grouping programs tailored for China, phase three contains analyses on the basic requirement of relevant policy and technology support to implement DRGs.

RESULTS: DRGs has been demonstrated to be an effective approach to manage health care insurance in many countries. Considering China’s special situations (population, health insurance system and policy environment), we developed and piloted DRGs in 12 tier-one hospitals in Beijing in 2010. We will further evaluate the impact of this program in the future.

CONCLUSIONS: The successful implementation of DRGs depends on an appropriate policy environment and mature technology support. DRGs is a complex system and has been divided into 3 stages. The first stage is the identification stage, the second stage is the implementation stage, and the third stage is the evaluation stage. In Beijing, the DRGs project will be implemented in 2011.

Health Care Use & Policy Studies – Drug/Device/Diagnostic Use & Policy

%PHP7

DEVELOPING PUBLIC HEALTH GUIDANCE – WHAT ARE THE DATA GAPS?
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OBJECTIVES: Public health policy is understood to be a major determinant of overall population health. However, developing public health guidance can be difficult due to the lack of sufficient evidence on the effectiveness and cost-effectiveness of possible interventions. The objective of this study was to identify the major gaps in the evidence base that has been used to develop public health guidance.

METHODS: The gaps identified by the UK National Institute for Health and Clinical Excellence (NICE) in the evidence that was used for the development of their 31 public health guidance documents published in December 2010 were assessed and compared.

RESULTS: The most prevalent data gap, identified by 25 of the 31 guidance documents, was a lack of evidence on the effectiveness of public health interventions in specific subgroups of the population, particularly ethnic minorities, age subgroups and those from disadvantaged backgrounds. The second major gap in the evidence, discussed by 21 documents, was a lack of data specific to the countries of interest (in this instance, the UK). Nineteen documents noted a lack of cost-effectiveness evidence as a barrier to developing public health guidance and 4 of these specifically noted the difficulty of generating QALYs in the public health arena. Further major data gaps included a lack of well-designed studies (14 documents), a lack of long-term evidence (13 documents) and inconsistencies in the evidence of an intervention make it effective (9) and a lack of evidence on the relative effectiveness of interventions (8).

CONCLUSIONS: Research into public health interventions and its issue is of paramount importance. Researchers should focus efforts on identifying particular subgroups in which interventions are particularly effective or ineffective and on generating country-specific data. Cost-effectiveness data is particularly lacking; one solution would be to devise new methods of QALY measurement in public health situations.

%PHP8

PHYSICIAN SHORTAGE IMPACT ON PATIENT RX USE FOR SELECT CHRONIC CONDITIONS
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OBJECTIVES: This study investigated the extent to which geographic variation in adequacy of primary care and specialist supply explains variation in patient use of prescribed medications to treat chronic conditions.

METHODS: Generalized Least Squares regression with period random effects was used on a pooled data set of monthly (May 2006 to Oct 2010) IMS Health data for 360 Metropolitan Statistical Areas (MSAs) for the total monthly prescriptions per MSA for (1) Statins, (2) PPIs, (3) Anti-psych, and (4) asthma/COPD. Separate regressions were estimated by therapeutic category and by payer type. Explanatory variables include monthly: (1) size of the population with the chronic condition,(2) economic environment; (3) dummy event variables; and (4) level of Rx advertising. Estimates of the shortage of primary care providers and specialists in each State in 2010 are included as explanatory variables. For state-level shortfall, provider demand estimates were based on national healthcare use and delivery patterns applied to each State’s population controlling for demographics, rates of uninsured, and obesity rates.

RESULTS: There exists a direct correlation between estimated adequacy of primary care and specialist (cardiologist, gastroenterologist, psychiatrist, pulmonologist, and allergist) supply and volume of prescriptions. The patterns are relatively consistent across the three payer types. For the state-level shortfall of cardiologists is associated with 0.36%, 0.43%, and 0.79% decrease in Statin Rx volume for the commercially insured, Medicare, and Medicaid populations, respectively. Each 1% shortfall of primary care providers is associated with decreases in volume across the commercially insured (0.15%) and Medicaid (0.83%) populations.

CONCLUSIONS: This research suggests that controlling for economic and population risk factors, greater inadequacy of physician supply is associated with lower use of prescriptions for treating chronic conditions. Physician shortages disproportionately affect access to medications for the Medicaid population, followed by the Medicare and commercially insured populations.