Health Care Use & Policy Studies – Risk Sharing/Performance-Based Agreements

**PHP101**

**VALUE BASED PRICING: WHAT IS THE FUTURE FOR PATIENT ACCESS?**

**Schemes?**

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OBJECTIVES: In the face of universal budget restrictions, pricing of pharmaceuticals remains a divisive subject. The US government is increasing its involvement in healthcare provision and insurers will have more budget pressures due to increased coverage. In the UK, the government has proposed a value-based pricing approach which will potentially increase the availability of new drugs. The objective of this study was to determine the future for patient access schemes (PAS) in achieving affordable budget impact whilst not restricting patient access.

METHODS: 40 telephone interviews were undertaken with payers in the UK, US and Taiwan representing government agencies, HTA groups and insurers. We asked their perceptions of current US policies to promote value, improve affordability, strategies that could be used by manufacturers and likely future changes.

RESULTS: Results demonstrated that manufacturers will aim for a particular price or price threshold, if this is not accepted by payers or insurers, then the risk will be transferred to the patient. PASs might be proposed for manufacturers to establish that their product is cost-effective and to achieve revenue targets. UK payers will find it difficult to determine the level of weighting applied to different unmet needs or to assign various rewards on value.

Conclusions: PASs could be a method used to determine the level of value through monitoring outcomes, but administrative burdens need to be considered. In the US, market evolution will accelerate the uptake of patient access schemes. Taiwan is likely to introduce PASs approaches as a means to reduce expenditures and high cost drugs. UK payers are considering PASs to help achieve revenue targets. This study highlighted the need for a shared understanding of PASs to allow for a more informed discussion on implementing value based pricing.

**PHP102**

**WHICH CRITERIA ARE USED IN HEALTH CARE DECISIONMAKING AND PRIORITY SETTING? A LITERATURE REVIEW FOR AN INTERNATIONAL SURVEY OF DECISIONMAKERS**

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OBJECTIVES: Resource allocation is one of the most challenging issues faced by health policy decision-makers requiring efficient consideration of many factors. Objectives of this study are to identify criteria used in decisionmaking around the world.

METHODS: An extensive literature search was performed in Medline and EMBASE to identify articles reporting decision criteria. Bibliographies of relevant articles were also searched. Studies conducted with healthcare decisionmakers (e.g., policy, medical, technical, clinical, patients, proxies, or representatives of health care programs) were included. Criteria reported were extracted and organized using a classification system derived from the EVIDEM framework.

RESULTS: A total of 96 papers were included. 2790 records were identified through electronic searching. 243 additional records were identified through bibliographic hand searching, of these 2790 were excluded. 356 articles were assessed for eligibility and 40 articles were included in the study. Large variations in terminology used to defined criteria were observed. Terms with similar but different content were assigned to unique criteria which were classified in 9 different categories including: 1) health outcomes and benefits of intervention, 2) types of health benefit, 3) impact of disease targeted by intervention, 4) therapeutic context of intervention, 5) economic impact of intervention, 6) quality/uncertainty of evidence, 7) implementation complexity of intervention, 8) priority, fairness and ethics, and 9) overall context.

The most frequently mentioned criteria were: equity/fairness (33 times), efficacy/effectiveness (28), healthcare stakeholder interests and pressures (28), cost-effectiveness (23), strength of evidence (20), safety (19), mission and mandate of health system (17), need (16), organizational requirements and capacity (17) and patient reported outcomes (16). CONCLUSIONS: The data synthesized in this study will serve as the basis for development of an international survey of healthcare decisionmakers.

The ultimate objective is to develop multicriteria approaches to efficient healthcare decisionmaking and priority setting.

**PHP103**

**COMPARATIVE EFFECTIVENESS REVIEWS AND THEIR POTENTIAL IMPACT ON FORMULARY ACCESS IN THE UNITED STATES**

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OBJECTIVES: The Effective Health Care Program of the AHRQ (Agency for Healthcare Research and Quality) has sponsored various comparative effectiveness reviews. The outcomes of these reviews were examined to determine their impact on access of novel therapies in a selection of the largest US plans by lines covered (Aetna, United Health, Cigna, Kaiser, Wellpoint) using their online formulary databases.

RESULTS: ACEIs vs. ARBs, NSAIDs, anti-depressants, epoetins, PPIs vs. H2As, and statins were reviewed by the AHRQ. Some of these results were either inconsistent or inconclusive due to lack of evidence; however, several found efficacy and safety to be similar across agents in a class. As expected, access to these products within the largest US plans are also comparable. In certain instances, a specific product or class demonstrated superior efficacy or tolerability. PPIs showed greater efficacy than H2As in resolution of reflux disease, and more specifically, esomprazole demonstrated superior efficacy over omeprazole for relief of symptoms at 4 weeks. The impact on formulary access in the US. However, price and contracting, in addition to efficacy and safety are among the key determinants for plans. It will be necessary to continue monitoring these reviews moving forwards and attempt to filter out their direct impact on access of drugs over time.

**PHP104**

**CURRENT USES OF AND PERCEPTIONS ABOUT FDAMA SECTION 114**

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OBJECTIVES: Section 114 of the 1997 U.S. Food and Drug Administration Modernization Act (FDAMA) stipulates the conditions under which drug companies could promote health economic information to health care plans. This study examined current uses and perceptions about Section 114.

METHOD: We conducted a web-based survey of a convenience sample of 59 experts representing pharmaceutical companies and academia. We asked about their interpretation of, and experiences with, Section 114, as well as their views regarding the FDA issuing further guidance to advise pharmaceutical companies on making promotional economic claims to payers.

RESULTS: Thirty-three of the 59 experts (56%) completed the survey. Among pharmaceutical companies, outcomes, health economic information, and quality of evidence are among the key determinants for plans. It will be necessary to continue monitoring these reviews moving forwards and attempt to filter out their direct impact on access of drugs over time.

**PHP105**

**HOW ARE COVERAGE DECISIONS MADE IN PUBLICLY FUNDED HEALTH CARE PROGRAMS IN LOW- AND MIDDLE-INCOME COUNTRIES?**

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OBJECTIVE: Universal health coverage for all persons worldwide was the focus of the First Global Symposium on Health Systems Research (Montreux, Switzerland; Nov 2010). As part of a larger initiative sponsored by The Rockefeller Foundation to transform health systems (accessible, affordable, equitable), we studied how coverage decisions are made by publicly funded health care programs in low- and middle-income countries (LMICs).

METHOD: 38 countries were considered and using FDAMA Section 114 to make promotional economic claims for drugs, but 63% stated they were unclear about how to effectively create, approve or use Section 114 information. The reasons for not using Section 114 included: not feeling comfortable using the Section 114 (38%) or the fact that economic information not included in the product label (13%), and uncertainty about whether creating a Section 114 piece was worth the benefit (13%). 75% expected to use Section 114 to a greater extent in the future. 75% of outcomes director and 86% of academic experts stated that the FDA should issue guidance on Section 114, especially regarding what qualify as "health care economic information" and "competent and reliable scientific evidence." 69% of outcomes directors and 65% of academic experts agreed that the increased focus on comparative effectiveness research would increase Section 114 use.

CONCLUSIONS: Pharmaceutical companies are considering and using FDAMA Section 114 to make promotional economic claims for drugs, despite their diverse interpretations of the law. Direction from the FDA may clarify how companies could share a range of comparative economic information with health plans.

**PHP106**

**DISPARITY IN ACCESS TO NOVEL DIABETIC AGENTS FOR MEDICARE PART D VS COMMERCIALLY INSURED PATIENTS: INSIGHT INTO DOWNSTREAM EFFECTS OF CMS FORMULARY GUIDELINES FOR PDP'S**

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OBJECTIVES: This ethnographic survey on how coverage policies are being developed provides opportunities for LMICs to share their experiences with each other, and thus further develop and refine their programs to meet goals of accessible, affordable, and equitable health care for all.

Health Care Use & Policy Studies – Conцептуальные Публикации