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PHARMACEUTICAL INNOVATION: DEFINITION, AND MECHANISMS FOR REWARD.
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OBJECTIVE: To define the concept of pharmaceutical innovation, examine whether it merits reward, and identify mechanisms for its incentivisation.

METHODS: Whether or not a medicine is innovative depends on its novelty and the benefits it generates. Novelties require something new, original and perhaps ingenious and is a necessary, but not sufficient, requirement for innovation. Novel pharmaceutical attributes include: new target of pharmacological mechanism of action, new chemical structure, improved formulation, improved pharmacokinetics and efficient methods of production. Benefits depend on perspective. Whereas a patient would value health-related quality of life, life expectancy, safety and convenience, payers of healthcare (e.g. UK NHS) value legitimacy values of population health and cost-effectiveness. A society might additionally value non-health benefits such as attracting pharmaceutical company investment in skilled jobs, and social responsibility (e.g. environment, neglected diseases).

RESULTS: An effective vaccine developed in the UK against malaria would be considered highly innovative from a societal perspective, but not from an NHS perspective, as malaria does not affect NHS patients. CONCLUSION: Health benefits to NHS patients are already rewarded to (and in some cases beyond) the threshold for cost-effectiveness ($30,000 per QALY). There is no incentive for paying an additional premium. However, where benefits of innovation to society exceed the costs, there is an argument for reward. This should not be through price increases, but through taxation and patent laws. The Patent Box, which will decrease the corporation tax to 10% on profits in the UK patents is one such mechanism. Alternatively, a 'value-based' (patenting) scheme might vary patent duration according to the benefits achieved, as the clinical evidence matures from the time of licensing. This might benefit patients through the earlier introduction of generics when branded products are made available, reward genuinely innovative products, while still allowing the introduction of ‘me too to’ compete on price.

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A TYPOLGY OF OUTCOMES FOR HEALTH RESEARCH
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Measuring “outcomes” is at the heart of this Society’s mission and of efforts to improve health and health care delivery. Despite this central role, there is no common agreement upon definition as to what is meant by outcomes. For example, for some commentators, outcomes refer uniquely to quality-of-life and survival of individual patients; this thinking underlies the US Patient Centered Outcomes Research Institute. For others, including those doing economic evaluation, outcomes may refer to the average health benefit groups of patients. Yet others use “outcomes” to refer to aspects of functioning of the health care system. This lack of consistency does little to illuminate the challenges in equitably delivering timely, high quality, and affordable health care. In this presentation, the authors present a typology of outcomes for health research along with and relevant examples. At the most granular level, endpoints in randomized trials are often clinical outcomes which are characterized as immediately observable - “hard” - such as hospitalization, death or functional status, or latent - “soft” - such as quality-of-life, pain, or satisfaction. At the next level are health outcomes which are the results of care delivered in actual practice and can be subdivided into treatment outcomes which reflect the intended and unintended medical consequences of undergoing therapy, and patient outcomes which reflect the impact on patients of undergoing care in the real world. System outcomes can be thought of as the impact of delivering care to a group of patients measured using the degree of functionality of the health care system. At the highest level are societal outcomes, which measure the impact of health on the wellbeing of society. Consensus as to what is meant by “outcomes” would be an important step towards improving the quality of the discourse and critical thinking in this area.

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A NEW ANTI-REBATE LEGISLATION IN SOUTH KOREA: WILL IT WORK THIS TIME?
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OBJECTIVES: The objective of this study is to examine the potential impact of recent reform in anti-rebate law of drugs in South Korea. METHODS: It has been an old business practice that some doctors and pharmacists receive financial benefits from pharmaceutical companies and distributors in exchange for business favors in Korea. These kickbacks are considered "unethical and illegal drug rebates". The Korea Fair Trade Commission reckoned consumer damage caused by illegal rebates in the medicines market at about USD 46 billion accounting for about 20% of total pharmaceutical sales in the year of 2007. There are a couple of reasons why illegal drug rebate is so prevalent in Korea. First, the current drug pricing system guarantees relatively good prices for generic products which local companies focus on producing. They tend to leave relatively higher margins for innovator drugs. On top of that, there are lots of small scale suppliers relative to the pharmaceutical market size of Korea. Fierce competitions among drug suppliers force them to concentrate on marketing activities, often coupled with illegal rebates. Third, government has no control over the visits by drug company representatives to doctors' offices. In addition, almost no medical treatment guidelines which could effectively regulate doctor's prescription behavior exist. RESULTS: Previously, any illega marketing practice by drug companies led to criminal punishment of drug companies alone, leaving doctors and pharmacists untouched. Under the new legal framework, the punishment for illegal rebates now extended to doctors and pharmacists. By penalizing both rebate givers and receivers, it is hoped that the level of illegal rebate can be disappeared or substantially reduced from the Korean market. However, we need to see what might happen in the real market practices from now on.

CONCLUSIONS: Remaining issues with this anti-rebate reform will be explored in this study.

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ON-GOING MARKET ACCESS ADVICE A POSSIBLE SOLUTION TO HELP ENSURE LONG-TERM SUCCESS IN POST-MARKETING CLINICAL STUDIES: CROSS FUNCTIONAL TEAMS OR EXTERNAL CONSULTATION?
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OBJECTIVES: Manufacturers are under increasing pressure to conduct shorter clinical studies in order to bring new medicines to market as soon as possible, reduce exposure revenue maximization before loss of exclusivity. At the same time, authorities from markets across the globe have demonstrated increased interest in post-marketing real-life clinical data in order to help make decisions with regards to reimbursement of drugs as well as their positioning in the treatment pathway.

METHODS: Manufacturers are spending increasing proportion of their budgets to produce this post-marketing clinical data. It is important to ensure if the data that is being produced is close to the needs of the payers. In majority of instances, it is seen that the data being created is quite far from the expectations of authorities to where benefit it is being created. The data is typically considered for use in payer discussions only at the end of the clinical study when little flexibility is possible in the end-points and outcomes that will be demonstrated. Also, benefits such as considering early data cuts to present on-going benefit of this long term data is not usually evaluated.

RESULTS: Manufacturers, outcome research affairs teams tend to function independently with very little collaboration as a result of differing targets and budgets. This has made it difficult to have early focused input into clinical studies. This is particularly so if they are post-marketing studies involving teams with lower focus on payer needs compared to peri-launch market access teams. There is an increased need for greater cross-functional effort on producing clinical data to ensure efficient use. CONCLUSIONS: Involving an external market access agency that is able to advise on the production, analysis and use of post-marketing clinical data is seen to be the solution to this issue.

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TELL ME WHO YOUR FRIENDS ARE: *PEERS* IN COMPARING HEALTH CARE SYSTEMS
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Total health spending and its share in the social product have been staple indicators in assessing and comparing health care systems. Comparison of health care systems based on Euros and cents is limiting, however, since the health care system is not an artifact of the economy. Institutions shape societal values on health care leading to peculiarities even among health care systems that share traditions in terms of health care financing and delivery. This paper presents a framework to compare health care systems in a meaningful way that accounts for systemic differences and similarities using the empirical technique cluster analysis. The analysis follows a three-step procedure. A review of the literature will be conducted to identify major institutional indicators of any given health care system. Cluster analysis will then be employed using these indicators based on data of OECD member countries. Based on the isolated clusters using the “minimum description length” approach, “typical” health care system will be identified and described highlighting so-called leaders of the pack. At the heart of the performance of every health care system is the extent to which it is able to respond to the desire for a healthy life by members of society. This implies accounting for both efficiency, which investigates the link between the between health care resources and health outcomes, and effectiveness, which assesses the achievement of goals rather than choosing one over the other. Assessing health care systems against peers and over time would not only set systems apart given their shared intent of ensuring health by providing health care but may well engender learning and lead to a race to the top.

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ENDOGENOUS COST-EFFECTIVENESS ANALYSIS IN HEALTH CARE TECHNOLOGY ADOPTION
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Increased health care spending across developed nations, including the US, has put pressure on both public and private payers. The current literature has attributed this growth in spending as being largely due to technological change. To prioritize adoption of new technologies, so called cost-effectiveness analysis has been used as the main tool by third-party payers and, as a result, has generated perhaps the largest sub-field within health economics. In this paper we argue utilization of cost-effectiveness analysis is subject to a form of Lucas critique, the stated goals of the policy makers to materialize when those affected by it respond to it. In particular, we stress that cost-effectiveness analysis by payers invariably reflects prices set by producers rather than resource costs used to produce treatments. This implies that the “costs” in cost-effectiveness assessments depend on endogenous markups which are, in turn, influenced by demand factors of patients, doctors, and, most importantly, the cost-effectiveness policy used by payers to translate prices to adoption decisions. We argue this has two important implications. First, under...