PNS8
TARIFF PAYMENTS: AN INCENTIVE FOR BEST PRACTICE OR A FORM OF COMPENSATION?

Taylor M
York Health Economics Consortium, York, NYK, UK

This paper uses an illustrative case study to explore the potential impact that different tariff levels have on the likely uptake of a new technology. A case study is used to demonstrate the financial outcomes associated with the uptake of a new intervention for atrial fibrillation with does not require anticoagulation monitoring, compared with an older technology which does require additional monitoring. Importantly, the analysis is undertaken from three different perspectives within the NHS, namely 'the Provider' (i.e. a local hospital), 'the Commissioner' (regional authority) and the health system as a whole. Various levels of tariff payment are assessed, some of which reflect the 'true' cost of monitoring, and others that reflect values based on other incentives. In the example, it would be clearly beneficial for the NHS as a whole to approve the new therapy since it saves £50 per patient. However, this would not be in the Provider's interest since the Provider receives compensation for monitoring costs by way of a tariff. By switching to the new drug, the Provider would lose out on substantial income from tariff payments for monitoring that is associated with the older therapy. There is a small 'window' (in this case study, between £75 and £125) where the preferred decisions of the Provider *and* the Commissioner match that of the system as a whole. A value *above* this window will mean that the Provider prefers does not wish to use the new drug, whilst a value *below* this window means that the Commissioner prefers to stay with the older therapy. To create an optimal incentive, the tariff value should be set within a specific range, based on modelled outcomes. The important finding is that this range does not need to be based on the actual cost of the service which is being compensated.

PNS9
ADVERSE EVENTS ASSOCIATED WITH EXTERNAL REFERENCE PRICING IN THE USA

Bathija S,[1] Tang M,[2] Ngo N,[1] Macaulay R[2]
[1]*PAREXEL International, Horsham, PA, USA,* [2]*Parexel International, London, UK*

External or international reference pricing (ERP) refers to using the price of therapies in one or several other markets to set benchmarks for price expectations in your own market. While this is typically seen in the ex-US markets, there have been ongoing proposals with the current US administration around whether the ERP model can be used to regulate the price of certain therapies in the US, a largely free-pricing market for pharmaceuticals. In addition, the Democrat presidential nominee has proposed establishing an independent review board that will use ERP to assess and recommend limits for launch prices of specialty drugs not facing direct competition and a new public health insurance option that will negotiate prices with providers. Separately, it would also allow importation of drugs from other countries as long as they are considered safe by the U.S. Department of Health and Human services. The US market for pharmaceuticals is by far the biggest globally compared with the relatively small/fragmented size of many major ex-US markets; e.g., the OECD reported in 2015, US pharmaceutical spend was $373 billion, over six-fold greater than the biggest European market (Germany, $62 billion). Therefore, if ERP pricing was implemented in the US, manufacturers may be incentivised to maximise revenues by strictly demanding US levels of pricing in other markets, rather than reducing US prices. Further, in many markets, companies can give confidential discounts on the list price in certain markets to secure access but not impact other countries prices through ERP. Additionally, the US is often a first-launch market, so there will rarely be any international prices for reference at the time of US. In summary, plans to impose ERP in the US, risk having limited impact on US prices and may actually instead incentivise increased list prices or changes in other markets.

PNS10
RESEARCH IN THE COVID-19 ERA: ACCELERATING THE SHIFT IN THE RESEARCH PARADIGM FROM TRADITIONAL TOWARDS DIGITAL/VIRTUAL SOLUTIONS

Stein D,[1] Baltezegar M[2]
[1]*Evidera, London, GLS, UK,* [2]*Evidera, Wilmington, NC, USA*

Objectives: The COVID-19 pandemic has demonstrated the need to think innovatively in the design and conduct of real-world studies to ensure study continuity with minimal burden imposed on healthcare personnel. Virtual and technology-driven solutions are available, but wide acceptability and adoption have been slow. We describe opportunities and challenges with incorporating different virtual and digital solutions, and how they can be successfully integrated into different study designs. ***Methods:*** Qualitative assessment of the conduct of virtual de-centralised study designs and the use of technology to extract data from hospital EMR systems. Observed opportunities and challenges are delineated. Applied virtual and technology-driven solutions were evaluated based on receptivity for study incorporation, ease of implementation and success factors such as accuracy, reliability, and the ability to complete the studies on time. ***Results:*** Several types of virtual and technology-driven solutions can be implemented across a number of study designs as primary and/or risk mitigation study execution strategies. Opportunities included: reduced workload/responsibility of hospital staff, increased data accuracy and speed of collection, increased patient adherence and reduced burden, increased control over study delivery with reduced impact of extraneous factors. Challenges included: Slow adoption of novel approaches, delayed ethics/release of data approvals for studies that do not fit typical traditional approach, country requirements that impact ability to implement, not all EMR systems are compatible, and linkage across several data sources may be required. ***Conclusions:*** Virtual and technology-driven solutions can be successfully implemented to address a breadth of research questions pertinent to drive drug approvals and improve patient care. Given the variety of options available and the need to tailor solutions to specific study needs, pragmatism is necessary to ensure successful shift from traditional to virtual.

PNS11
SAFETY CHALLENGES IN THE PROCEDURES FOR ACCESS AND AFFORDABILITY OF INNOVATIVE TREATMENTS

Fens T,[1] van Puijenbroek EP,[2] Postma M[3]
[1]*University of Groningen,University Medical Center Groningen, Department of Health Sciences; Groningen Research Institute of Pharmacy, Groningen, GR, Netherlands,* [2]*University of Groningen, Groningen Research Institute of Pharmacy; University Medical Center Groningen, Department of Epidemiology, Groningen, Netherlands,* [3]*University of Groningen, University Medical Center Groningen, Department of Health Sciences & SHARE; Faculty of Economics & Business, Department of Economics, Econometrics & Finance, Groningen, Netherlands*

Innovative treatments, such as gene- or immunotherapy, provide promising solutions warranting accelerated approval. Yet, in general accelerated approvals may pose safety challenges. Among the processes for access and affordability of such treatments information on safety may be less than we are used to in non-accelerated procedures. Here, we investigate to what extent existing procedures satisfy the needs of safety assessment in the healthcare system and how potential existing safety gaps can be addressed. A pragmatic review was carried out to identify relevant literature, using PubMed as a search platform to explore MEDLINE and snowballing as an additional method for further search. There is a trend that solutions for accelerated access for innovative treatments are implemented in models of regulatory approvals, yet with limited data. Besides efficacy data, providing adequate safety data is key to transferring conditional- to final marketing authorization. However, this remains a challenge because of the restricted availability and transferability of such data. An example to overcome such issues is the International Coalition of Medicines Regulatory Authorities (ICMRA) who provide equitable access to global clinical trials data regarding COVID-19. Similarly, HTA bodies and manufacturers are overcoming clinical data issues in the Sharing European Early Dialogs (SEED). Many countries re-invent multi-criteria decision analysis (MCDA) as alternative to focus on (cost-) effectiveness only, yet eligibility, clear criteria, choosing the right model, and outcomes interpretation remain challenges. With managed-entry agreements (MEAs), access barriers between manufacturers and health authorities can be are overcome in conditional access situations. Although a growing trend of outcomes-based MEAs is noticed, financial-oriented MEAs remain dominant, and those MEAs that are outcomes-based focus on effectiveness rather than safety. Safety may be an aspect undervalued in accelerated access procedures. We notice and suggest increasing use of MCDA and MEAs also focussing on safety in real-life conditional access situations.

PNS12
PILOT PARALLEL PROCEDURE MARKETING AUTHORISATION AND HTA IN THE NETHERLANDS

Liebrand K,[1] **Pasman P**[2]
[1]*CBG-MEB, Utrecht, UT, Netherlands,* [2]*National Healthcare Institute, Diemen, Netherlands*

In the Netherlands the Medicines Evaluation Board (MEB) assesses the quality, efficacy and safety of a medicine before issuing a marketing authorisation and the National Health Care Institute (ZIN) then assesses whether the registered medicine is eligible for reimbursement via the standard health care package. In the Netherlands the MEB and ZIN have joined forces to shorten the time from registration up to the moment that medicines are reimbursed in the "pilot Parallel Procedures MEB-ZIN." As indicated by the name: a more parallel procedure for authorisation and reimbursement trajectories, instead of the current sequential process. This entails that the procedure for reimbursement starts before the marketing authorization has been granted. In order to facilitate such an approach, the MEB provides context and background information on the assessment and shares information and gained knowledge with ZIN. Furthermore, in the pilot procedure pharmaceutical companies are able to discuss reimbursement in early pre-meetings. The overarching goal is to develop a new method for parallel assessment to increase patient access to new medicine. In this project pharmaceutical companies have dedicated their products to be used in this parallel procedure. In November 2019, the first procedure in the project was started. Normally, the procedure for reimbursement could have started, after publication of the European Assessment Report (May 27th, 2020). However, in this pilot procedure, the procedure for reimbursement was finalized one week later (early June), demonstrating that the parallel approach for registration and reimbursement is feasible and greatly enhances patient's access to new medicines by shortening the time from registration to reimbursement. In the pilot the parallel assessment method is tested by more products to come to national recommendations, which could be internationally integrated.