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OP19 Unlocking The Potential Of Established Products: Need For Incentives

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INTRODUCTION:

Re-purposing of established products (EPs) – defined as marketed for 8 years or more – may represent a high value for patients and society. It has been recognized by the European Commission as an important factor contributing to greater access to new therapies. Due to a lower development cost, it could also represent a cost-effective alternative and help to reduce pressure on healthcare budgets. However, it is perceived that no financial incentives exist for the pharmaceutical industry to invest in new indications for EPs. The objective of this research was to review current European regulations and propose strategies stimulating development in this field.

METHODS:

We performed a targeted literature review and held two international expert panel workshops to discuss current policies and their implications, and issue recommendations for changes.

RESULTS:

Within the current regulatory framework EPs face price cuts due to generic competition, reference pricing (RP), price re-negotiations or systematic price cuts, after a period of marketing presence. Extension of indications

does not permit to increase or maintain the price. Generic substitution regardless of indication poses another challenge. Limited incentives in the form of an additional year of market protection exists only for new indication(s) registered within the first 8 years following initial approval. The expert panel proposed several strategies to stimulate development in this field, including: (i) extending the period in which registering a new indication results in additional market protection beyond 8 years and extending the duration of additional market protection; (ii) delaying inclusion in RP for EPs with a new value adding indication; (iii) establishing a differential pricing by indication; (iv) preventing temporarily generic substitution when an EP is prescribed for a new indication.

CONCLUSIONS:

Current regulations represent a serious disincentive to develop new indications for EPs. Regulatory and pricing policy changes are needed to stimulate development in this important field.

OP21 Involving Clinical Experts In Prioritizing Topics For Health Technology Assessment: A Randomized Controlled Trial

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INTRODUCTION:

The National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme commissions research to inform health services in the United Kingdom. The program prioritises research ideas from literature, guidelines, patients, and clinicians, to decide which research should be funded. We get clinical input on these ideas through (i) committees of clinicians and patients and (ii) seeking written advice from multiple clinicians — a refereeing process. Chairs of our committees suggested that the material we sent to clinicians was too extensive and the method of

response too burdensome. We set out to determine whether reducing the information provided or burden of response would improve the engagement of clinicians with our processes, and hence improve the quality of advice provided, and the research available to health services.

METHODS:

We undertook a factorial randomized controlled trial (University of Southampton Faculty of Medicine Ethics Committee #8192, Trial registration: ACTRN12614000167662). Each participant was randomized to receive one of two types of material to comment on, and one of two means to respond. In the first allocation participants were randomised in a 1:1 ratio between receiving a 'vignette' (a briefing paper of up to ten pages discussing possible research = usual practice), or a 'commissioning brief' (a single page summarising the proposed research). In the second allocation, the method of response was randomized, between a structured form and free text email.

RESULTS:

We randomized 460 clinical experts, and 356 (77.4 percent) responded. The responses were graded for quality on a scale of 0 to 4 (higher scores better). Non-response was scored as 0. Analysis using ANOVA gave results of a structured response scoring .34 points (Standard Deviation, SD .36) over a freeform response ($p = .02$); and the commissioning brief as .04 points over a vignette ($p = .81$).

CONCLUSIONS:

This was the first randomized trial to take place inside the secretariat of the HTA program. The difference in quality score between the brief and the vignette allocations was neither statistically nor practically important. The difference between the structured and freeform response was statistically significant, and sufficiently large to be important in practice. While the choice of material to share with clinicians seems unimportant we have shown that it is worth sending a structured response form to experts.

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OP22 Societal Perspective On Cost Drivers For Health Technology Assessment

AUTHORS:

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INTRODUCTION:

Understanding cost drivers and estimating societal costs are important challenges for economic evaluation of health technologies in low-and-middle-income countries (LMICs) (1). This study assessed community experiences of health resource utilization and perceived cost drivers from a societal perspective to inform the design of an economic model for the Community Level Interventions for Pre-eclampsia (CLIP) trials (2).

METHODS:

Qualitative research was undertaken alongside the CLIP trial in two districts of Sindh province, Pakistan. Nine focus groups were conducted with a wide range of stakeholders, including pregnant women, mothers-in-law, husbands, fathers-in-law, healthcare providers at community and health facility-levels, and health decision-/policy-makers at the district-level. The societal perspective included out-of-pocket (OOP), health system, and program implementation costs related to CLIP. Thematic analysis was performed using NVivo software.

RESULTS:

Most pregnant women and male decision makers reported a large burden of OOP costs for in- and out-patient care, informal care from traditional healers, self-medication, childbirth, newborn care, transport to health facility, and missed wages by caretakers. Many healthcare providers identified health system costs associated with human resources for hypertension risk assessment, transport, and communication about patient referrals. Health decision-/policy-makers recognized program implementation costs (such as the mobile health infrastructure, staff training, and