teams and stakeholder communities supported the PBMAs which were executed over a 12 -18 month period between 2013–15. Group decision support methods were used to facilitate meetings and decision making. Formal interviews with project team members and informal feedback informed development of the final PBMA framework.

RESULTS:

Identifying the costs and resources attributable to services and those that could be moved around services was challenging. Evidence of outcomes and 'health value' was more easily available. One PBMA pilot recommended that some modest service reorganization and quality improvement could be made within budget but no substantial improvement/decommissioning could be undertaken. The other pilot agreed a disinvestment decision on the basis of evidence and reallocated the resources to a higher value service. The HB commissioning team found the information from the PBMA 'journey' as useful as the recommendations. A PBMA framework for the HB was devised.

CONCLUSIONS:

A 'Prudent PBMA' framework trimmed back to the critical essentials enables success criteria to be met. PBMA is to be adopted as a 'way of working' to operationalize resource reallocation and disinvestment in the 'real world' of Welsh healthcare commissioning.

OP100 How Health Technology Assessment Is Adapting To Orphan Drugs In Canada – Not!

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INTRODUCTION:

Some countries have distinct pathways for drugs for rare diseases (DRDs) (1). In May 2014, the Canadian Agency for Technologies in Health (CADTH) rejected the option of a separate review pathway for DRDs, reiterating that "pharmacoeconomic analyses are critical for all types of drugs". While the gap between positive recommendations for common and rare drugs may have narrowed, the rejection for DRDs is still proportionally much higher (2). The default has been to provincially negotiate drug access, for patient populations, subgroups or individuals. Still not wishing to create a separate pathway, in March 2016, CADTH produced a revised evaluation framework for "uncertain clinical and pharmacoeconomic evidence" and other considerations representing "significant unmet need" including rarity and difficulty to study because of small patient population"(3). This study analyzes recommendations for DRDs following the two CADTH revisions.

METHODS:

Methods used were: synthesis of previously conducted analyses of CADTH recommendations for rare and non-rare drugs, primary comparative analysis of CADTH recommendations for DRDs from 2004 to 2016, and qualitative analysis of two drugs submitted for both rare and non-rare conditions: everolimus (breast cancer, pancreatic neuroendocrine tumours, and tuberous sclerosis complex) and ibrutinib (chronic lymphocytic leukemia, small lymphocytic lymphoma, and Waldenström's Macroglobulinemia).

RESULTS:

Previous analyses found that DRDs received more negative recommendations than did non-rare drugs; both clinical and economic evidence were differentiating factors. The primary analysis provided an additional understanding of reasons for negative recommendations. There is low consistency across assessments and across the two CADTH review committees. The case studies illustrated the challenges for DRDs to overcome barriers of cost-effectiveness and certainty of clinical evidence, even with the revised framework.

CONCLUSIONS:

This research challenges the premise that Health Technology Assessment for all drugs can result in fair and equitable recommendations for DRDs. Moreover,

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assessments based on "significant unmet need" do not appear to provide consistent or equitable guidelines for addressing the issues specific to rare diseases.

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OP101 Do We Need To Extend Health Technology Assessment To Health Enhancement Assessment?

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INTRODUCTION:

Several health technologies used for therapy can also be used for health enhancement. Drugs stimulating cognitive abilities are but one example. Health Technology Assessment (HTA) has not been developed for assessing enhancements. This raises the question of how HTA should address the blurred distinction between therapy and enhancement. Should we (i) carve out a distinction between therapy and enhancement and limit HTA to therapy, (ii) use HTA for both therapy and enhancement (with some modifications), or (iii) should we develop a separate health enhancement assessment (HEA)?

METHODS:

A literature search of the medical, philosophical, and bioethical literature was conducted for debates, arguments, and suggested solutions to the issue of therapy versus enhancement.

RESULTS:

The same improvement in health may be therapeutic in one patient, but an enhancement in another. Moreover, both therapy and enhancement share the same goal: increased health and wellbeing. A wide range of arguments try to establish a difference between therapy and enhancement. They refer to naturalness, rehabilitation, normality, species-typical functioning/potential, disease, sustainability, and responsibility. On closer scrutiny few of these arguments do the job in bolstering the therapy-enhancement distinction. We already use a wide range of means to extend human abilities. Moreover, the therapy-enhancement distinction raises a wide range of ethical issues that are relevant for the assessment of a number of emerging health technologies.

CONCLUSIONS:

Existing HTA methodology can address a wide range of non-therapeutic health enhancements. However, a series of broader issues related to the goal of health care and responsibility for altering human evolution may not be addressed within traditional HTA frameworks. Specific HEAs may therefore be helpful.

OP103 CONITEC's Rapid Reports As Technical Support In The Litigation

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