PP123 Fair Drug Pricing: Review Of Literature And Models

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Introduction. Constantly rising costs of pharmaceuticals and biologics spurred a debate in recent years leading to increasingly persistent public calls to overhaul the existing system of pricing and distributing health technologies. The COVID-19 pandemic exposed the controversies of the current model of access to health commodities in all evidence when the existing discrepancy between the global supply and the global demand in health technology can be viewed as an illustration of a conflict between the neoliberal free market ideal of health innovation genesis and ownership and the original democratic principles of what would now be called sustainable human development.
Methods. Presented here is an integrative literature review of over 265 publications in peer-reviewed journals on Pubmed and Web of Science, academic and "grey" literature, mainly publicism, published in English. We reviewed and analyzed included literature for the purposes of identifying leading ideas with regards to ethical frameworks for evaluating or referencing value for pricing health commodities.
Results. Seven drug pricing models were analyzed in terms of them satisfying the three most common criteria of price adequacy – its fairness (viewed from the point of view of main schools of ethical thought), accountability-for-reasonableness (including transparency of decisions, relevance, existing mechanisms of revisions and governance to ensure compliance), and price functionality. One of the central ideas under controversy is value, its relative character for different contexts due to the high weight of the willingness-to-pay in the value-based health technology assessment (HTA) decisions and the relative value of money, and the attempts to quantify value in a universal way for institutions, patients, and originators.
Conclusions. While the review scored the pricing models on their "public fairness" with volume-based rather than value-based pricing models leading the rating, the main conclusion of the review is that the main meaningful divide is between value creation and value extraction when pricing health innovation.

PP124 The Importance Of Flexible PPI Approaches: Case Study On Flash Glucose Monitoring

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Introduction. Health Technology Wales (HTW) review guidance 3 years after publication to establish if reassessment is warranted because, for example, new evidence has become available. Since the publication of guidance on flash glucose monitoring (FGM) in 2018, HTW introduced a patient and public involvement (PPI) process with novel approaches to flexible engagement. This enabled HTW to include three streams of patient evidence into the review of FGM devices.
Methods. HTW's Patient and Public Involvement Standing Group (PPISG) considered appropriate methods of engagement using the HTW Patient and Public Involvement Mechanism Tool. This tool considers the nature of the health technology, the presence of appropriate patient organizations and questions that can be put to patients, as well as other approaches for obtaining patient evidence.
Results. HTW contacted Diabetes Cymru and met with them to discuss contributing to the appraisal of FGM devices. Diabetes Cymru produced a patient submission summarizing the experiences of their patient network, with particular focus on the expansion of the technology to closed-loop insulin systems. Diabetes Cymru later attended HTW's Appraisal Panel committee and gave a presentation. Additionally, HTW conducted a patient evidence literature review. This review summarized published qualitative studies on a range of perspectives, including carer perspectives, family perspectives, children and adolescences perspectives as well as considerations from specific environments, such as schools, workplaces, homes, care homes and communities. In addition to new clinical and cost effectiveness evidence, this PPI input was used to formulate new guidance recommending more widespread adoption of FGM.
Conclusions. The introduction of flexible approaches to PPI enabled HTW to gain patient evidence from multiple sources. This ensured greater patient representation and a more detailed understanding of the role of FGM devices across different patient communities. This added considerable richness to the patient evidence, which is vital to understand the everyday impacts of FGM and its use amongst patients. Combining flexible PPI with the new clinical and cost effectiveness evidence resulted in a change in the original guidance recommendation.

PP125 Economic Evaluation Of Molecular Diagnostics – A Review And Future Directions

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Introduction. It has been suggested that health economists need to adapt their methods in order to meet the challenges of evaluating molecular diagnostics. The aim of this review is to categorize and critically examine the challenges and methodological developments identified from the literature and to suggest how such challenges may be addressed.
Methods. We identified challenges and suggested methodological improvements using a systematic rapid review of the literature. We categorized challenges into those common to all economic evaluations, those common to all diagnostic technologies and those relevant to molecular diagnostics. We assessed whether development in the methods of economic evaluation or alternative action was required.

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Results. We found forty-one papers which identified twelve challenges. Choice of perspective and time-horizon were challenges common to all economic evaluations. Five challenges were relevant for all diagnostic technologies: complexity of analysis; range of costs; under-developed evidence base; behavioral aspects; and choice of outcome metrics. The final five challenges were specific to molecular diagnostics: heterogeneity of tests and platforms; increasing stratification; capturing personal utility; incidental findings and spill-over effects. The final five challenges may require methodological development. For example, although methods exist to capture the value of a diagnostic test over and above any health gain captured in a quality adjusted life year ('personal utility'), there is currently no agreed method of incorporating this into a cost-utility analysis. For the other challenges development of evaluation processes is key. In particular, the weak evidence base for diagnostic technologies may require processes to evolve.
Conclusions. Current methods of economic evaluation are generally able to cope with molecular diagnostics although a renewed focus on specific decision-makers' needs and a willingness to move away from cost-utility analysis may be required. A key issue is the under-developed evidence-base and it may be necessary to rethink translation processes to ensure sufficient, relevant evidence is available to support economic evaluation and adoption of molecular diagnostics.

PP126 Direct Patient Involvement In HTA In Canada And Brazil: The Patients' Perspectives

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Introduction. Since 2019, Canada's Drug and Health Technology Agency (CADTH) has worked directly with patients through its Patient and Community Advisory Committee (PCAC). In Brazil, Conitec has worked directly with patients since 2021 through testimonials in its committee meetings for all assessed technologies. In this study we explored patients' perspectives about their participation in these processes.
Methods. Two patients directly involved with both CADTH and Conitec were invited to share their perspectives about the strengths and weaknesses of the patient engagement processes.
Results. For CADTH, the strengths were as follows: PCAC focuses on the whole organization, including the patient engagement strategy and strategic plan, and is on the same level as other professional committees; PCAC members are compensated; the 'Learning Sessions' show CADTH staff the ramifications of their work in people's lives; and there is increased patient engagement on other committees throughout CADTH. The weaknesses identified with the CADTH process were that PCAC is an advisory body with no decision-making authority and that the diversity of people on the PCAC could be increased. In addition, while CADTH informs and consults patients, the PCAC is not involved in individual HTAs.

The strengths of Conitec's process were that the volunteer is selected by patients; there are opportunities to consolidate direct patient involvement and promote it in other instances; and the technical support is excellent. On the downside, there was a lack of information about this opportunity; the testimonials last only ten minutes and patients are frequently not questioned; only one patient can participate; there is a lack of transparency about testimonial analysis and its role; and being the only representative during a discussion that culminates in a decision can cause anxiety about performance.
Conclusions. Patients felt heard in the engagement processes and stated that the PCAC embeds patient perspectives throughout CADTH, not just in particular HTAs. One patient felt that her participation was essential for the committees to understand patients' lived experiences.

PP127 Impact Of Brazilian Patient Testimonials On Medical Devices And Public Confidence In The Healthcare Decision-Making

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Introduction. Since October 2020, Conitec has made public calls (PCs) to invite patients and family members to express perspectives during committee meetings. This study seeks to reflect about the impact of the newest patient and public involvement (PPI) Conitec strategy and how it can contribute to increase patient direct involvement and public confidence regarding Brazilian health decisions in medical devices.
Methods. We conducted a document analysis after searching for PCs addressed to medical devices in the section "Patient Perspectives" on Conitec´s website until Aug 31, 2021.
Results. From 64 PCs, five were related to medical devices. Rotational thromboelastometry for transfusion controls: Ended upon applicant request. Transcatheter aortic valve implantation (TAVI): One patient gave his testimonial, explaining how it impacted his quality of life and daily activities, besides answering questions from the committee. The testimonial was not included in the recommendation report. After the public consultation, the initial recommendation changed from non-reimbursement to reimbursement. Botton™ probe for gastrotomy: Eleven people volunteered and a family member was selected. She expressed the importance of the device in her son's quality of life, making ordinary activities more accessible, helping in the physiotherapy sessions, reducing hospitalizations, and supporting her son's socialization. The initial recommendation was to reimburse it. iStent Inject Trabecular Micro-Bypass System™ (glaucoma treatment): No patients volunteered. The final recommendation report informed that Conitec received 55 comments through public consultation, including experiences and opinions about the technology. After the public consultation, there was a change from the initial to the final recommendation, from non-incorporation to incorporation. Non-invasive ventilation (cystic fibrosis treatment): There were five volunteers and a mother of twins, both with cystic fibrosis, gave her testimonial. She expressed the importance of this device in her kids' quality of life, allowing them to sleep better, eat and study, control the symptoms, and reduce hospitalizations and antibiotic usage.

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