Introduction. The Brazilian health technology assessment (HTA) process includes calls for public consultations, in which society can give its opinion on reports emitted by the National Committee for Health Technology Incorporation (CONITEC). Open and closed queries for public consultation are performed by official formularies and can be accessed online at CONITEC webpage. Queries are divided into two categories of reports: clinical protocols and guidelines, and incorporation/exclusion demands. Incorporation/exclusion queries are subdivided in two additional categories: opinion and experience, or technical. In this study we analyze the weight of patients' participation in opinion and experience queries and their opinion (pro or con) on inclusion/exclusion of health technologies.
Methods. Formularies concerning concluded public consultations on health technology incorporation/exclusion reports were extracted from CONITEC website from 1 January to 26 November 2021. Entries on the opinion and experience formularies included amongst others, a close-ended question about the opinion of participants on health technology incorporation/exclusion reports ("favorable"/"against"/"neither"). In this study, we analyzed patients' opinion contained within concluded public consultations on incorporation/exclusion of health technologies.
Results. A total of 63 health technology incorporation/exclusion queries were performed in the analyzed period, of which there were only four exclusions. A total of 32,209 contributions were registered. "Patients", "Health professionals", "Family or caregivers", "Interest on the theme", accounted for 99.4 percent (13.5, 16.7, 32.3, 36.7%, respectively). Patient participation accounted for 4,367 (13.5%) entries. The total number of opinions in favor of the presented documents by the "Patients" was 4,268 (97.7%), 59 (1.4%) disagreed and 40 (0.9%) had no opinion.
Conclusions. Public consultation of official HTA reports is a very useful tool to legitimize decisions through social participation. Although patient participation is not numerically the most important category to contribute on public consultation queries, patients are, if not the most influential stakeholder, the main recipient of decisions concerning health technologies incorporations. Further analyses shall investigate experience narratives included in public consultation queries.

OP63 Patient and Public Perspectives On The Scottish Medicines Consortium Detailed Advice Document

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Introduction. The Scottish Medicines Consortium (SMC) conducts early health technology assessment (HTA) of new medicines, the primary output of which is a document referred to as the Detailed Advice Document (DAD). This comprises an overview of all data considered on the clinical and cost-effectiveness of the medicine, as well as the input from patient groups (PGs), patients, and carers. In 2020, SMC commenced a stakeholder evaluation of the DAD including a workshop with PGs and public partners (members of the public who volunteer with SMC) to explore the potential for using the DAD more widely.
Methods. PGs and public partners, all having significant experience of engaging with SMC, participated in the workshop. Feedback was gathered using virtual post-it notes, collated and analysed for key themes. We also gathered oral feedback from participants. Sample DADs were distributed for two medicines recently appraised, one of which included a Patient and Clinician Engagement (PACE) meeting. These were chosen because they reflect different aspects of public and patient involvement at SMC, including how this is presented in the DAD.
Results. Overall, the workshop participants (n=7) recognised the DAD was a useful document for the clinicians who are its primary audience. Its language was perceived to be challenging, including complex information that is not accessible to a wide audience and may only be fully understood by those with a good understanding and knowledge of HTA. This was a key barrier to using the DAD more widely, in particular the health economics information. Suggestions for broadening the audience of the DAD included summaries of key points and an introductory section clarifying the purpose of the DAD and its intended audience, along with signposting to the plain language summary produced by SMC. These will be implemented where possible.
Conclusions. Improving how SMC communicates decisions to patients and the public, by working in partnership with these stakeholders, will help strengthen public involvement throughout the HTA process.

OP64 NICE Listens: Engaging The Public On How To Address Health Inequalities In Health Technology Assessment And Guideline Development

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Introduction. Involving and engaging the public is an essential step to engender trust and confidence in HTA organizations. In 2021 the National Institute for Health and Care Excellence (NICE) launched NICE Listens, a new programme of deliberative public engagement seeking to address topics that have complex social, moral, or ethical dimensions. Health inequalities (HI), defined as unfair and avoidable differences in health across populations, was the first topic. The aim was to understand how the public would like NICE to act in regard to HI. Despite repeated attempts to tackle HI in England, the gaps in life expectancy between the most and least deprived continue to widen. NICE has committed to addressing HI in its five-year strategy and NICE Listens forms part of a comprehensive engagement strategy to understand how best to do this.

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Methods. Twenty-eight (28) members of the public from across England took part in four iterative two-hour online workshops, held fortnightly in late 2021. They consisted of both plenary and breakout sessions and incorporated a range of stimuli including trade-off exercises and interview clips with HI experts.
Results. The findings show clear public support for HI being a high priority for NICE, albeit with limits on how and when HI should be addressed. Actions towards reducing HI should focus on supporting a preventative and systemic response. Importantly, there is a need for a transparent process for incorporating HI within NICE guidance as well as rigorous staff training in understanding and addressing HI. Recommending technologies that benefit the majority even when not accessible for all is acceptable if there are clear plans to manage access gaps.
Conclusions. Reducing health inequalities should be a high priority for NICE and other HTA organizations. Organizations should seek to have clear processes for embedding HI in decision-making. Priority should be given to actions that focus on prevention of ill health and those that have wider system impacts.

OP65 An Overview Of Participatory Approaches, Stakeholders, Methods, Topics and Challenges In Medical Device Development: A Scoping Review

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Introduction. Stakeholder involvement in medical device development draws much attention. To make well-considered methodological choices while involving stakeholders, it is essential to know what approaches are available and what challenges they bring in practice. Therefore, the aim of this review was to study which participatory approaches are used in the early stages of the lifecycle of medical device development, and to describe the most important characteristics of these approaches.
Methods. We conducted a scoping review and searched PubMed, Embase and Web of Science for articles published between July 2014 – July 2019. Papers were included if they presented original research featuring any form of stakeholder participation in the development of medical devices. We used The Spectrum of Public Participation to categorise the approach of each paper. We describe four characteristics of each approach: the stakeholders involved, data-collection methods, topics addressed, and the challenges associated with the approaches as perceived by the researchers.
Results. From the 14,838 papers from the initial search, 278 were included. All papers could be categorized into three levels of participation: collaboration, involvement, and consultation. The results show that patients and healthcare professionals are most frequently engaged in all approaches, besides stakeholders like citizens, relatives, and experts. The most often used data-collection methods are workshops in the collaboration approach, and interviews in the involvement and consultation approach. Topics addressed in all approaches are: the initial problem, requirements of devices, design choices, testing of devices, and procedural aspects of the involvement. Challenges in the approaches are related to sampling, analysis, social dynamics, feasibility, and closure.
Conclusions. This review shows that despite the abundance of methods mentioned in literature, there are three main approaches to involving stakeholders in device development: collaboration, involvement, and consultation. These mainly differ in the degree of power that is granted to stakeholders, but are comparable in terms of data-collection methods, stakeholders, topics, and challenges.

OP67 Considerations Of Treatment Novelty In Health Technology Assessment

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Introduction. A recent proliferation of value frameworks, as well as the emergence of innovative approaches to treating disease (e.g., cell/gene therapies) have been accompanied by an increased focus on nontraditional elements of value. We sought to understand whether and how health technology assessment (HTA) agencies consider novel aspects of treatment in value assessments.
Methods. We defined treatment novelty as follows: (i) a new mechanism of action or administration; (ii) addresses an unmet need; or (iii) confers a distinct benefit that transforms clinical practice or that is difficult to quantify. We reviewed technical guidance and peer-reviewed literature to investigate how organizations in eight countries (Australia, Canada, England, France, Norway, the Netherlands, Sweden, and the United States) consider aspects of this definition.
Results. All (n = 8) organizations give special consideration to interventions that address an unmet need, particularly in cancer, rare diseases, and other severe conditions. Nearly all (n = 5) organizations consider whether an intervention produces benefits that may not be adequately quantified. Organizations in England, Norway, and France sometimes recommend drugs with less favorable cost-effectiveness estimates than traditionally considered if the drug addresses rare or severe conditions, or if its quality-of-life benefit is thought to be inadequately quantified. The Institute for Clinical and Economic Review in the United States models cost-effectiveness in rare diseases using both a modified societal and health care system perspective. Importantly, the benefits of novel treatments are frequently considered uncertain, particularly treatments with a new mechanism of action. When uncertainty is high, organizations in Canada, England, France, the Netherlands, and Sweden sometimes issue conditional recommendations until additional evidence is submitted. England and Australia have used risk sharing agreements for drugs determined to be novel but uncertain.
Conclusions. The most widely considered aspects of treatment novelty in HTA are unmet needs and potential benefits that are not easily measured. The willingness to pay for novel treatments is often greater, despite inherent uncertainties about benefit and cost-effectiveness.

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