OP75 Facts And Values In Health Technology Assessment: The Case Of Non-Invasive Prenatal Testing

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Introduction. Health Technology Assessment (HTA) is where facts and values meet: the evidence that is considered relevant to the assessment of a technology depends on the value framework used. In the context of the European project VALIDATE (Values in doing assessments of healthcare technologies), we assessed to what extent this interplay between facts and values is acknowledged in HTA reports on non-invasive prenatal testing (NIPT). Our aim is to gain a better understanding of this fact-value relationship, and to contribute to the development of capacity for ethical analyses in HTA.

Methods. Five reviewers independently analyzed HTA reports on NIPT, obtained from the National Institute for Health Research (NIHR) HTA database, by answering a structured questionnaire on: (i) arguments, values, and conclusions; (ii) relations between values and collected evidence; (iii) operationalizations of the values involved. Ethical argumentation was analyzed using the method of specifying norms. This method holds that for general, abstract ethical principles to reach concrete cases, principles need to be specified in such a way as to achieve maximal coherence between different value commitments and practice. The results of the analysis were discussed in joint meetings to arrive at a consensus on interpretation.

Results. Our results show that the pivotal role of values in defining what counts as relevant evidence and why, is rarely acknowledged. The same holds for the importance of specifying values as a means to achieve greater coherence between the use of healthcare technologies and a range of values.

Conclusions. There is ample room for improvement in clarifying the role of values in HTA: they can serve to explain and justify what evidence is considered relevant to the assessment of a healthcare technology. Recognizing that abstract values need specification in order to reach concrete cases opens up new opportunities for exploring in what way values are affected by healthcare technologies.

OP77 Nudging In Non-Invasive Prenatal Testing: Ethical Guidance

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Introduction. Non-Invasive Prenatal Testing (NIPT) has already established itself in many European countries (either via public or private institutions) as an option at hand that pregnant women can choose. Based on mother's blood, NIPT claims to "quasi-diagnose" among other things the presence of chromosomal abnormalities caused by an aneuploidy of a chromosome (such as Trisomy 13, 18, and 21). Apart from normative issues concerning the question of "whether to fund NIPT by universal coverage", NIPT gives rise also to normative issues concerning the question of "how to put NIPT into practice" – the analysis of which is the goal of this study.

Methods. Complemented by a hand search, we have conducted a systematic literature search in Ovid MEDLINE and PsycINFO for combinations of NIPT and nudging, NIPT and participation, and NIPT and ethics. Screening was based on content analysis of titles, abstracts, and articles. Writing of the study is in progress.

Results. We identified 83 references of which 39 were included. The main instance of nudging (or also of unintentional choice design) was the use of default bias (the application or reduction of friction cost/hassle factor) that influenced the turnout to NIPT. In establishing NIPT in universal coverage systems, further potential biases identified were the use of authority bias, bandwagon effect, sunk-cost bias, and framing effect. The core ethical challenges with nudging in NIPT derive from the lack of transparency of the methods applied and the challenge of paternalism.

Conclusions. Along the line of accountability for reasonableness, four specific recommendations are suggested as the ethical guidance to using of the tool of nudging in NIPT: (i) decision makers should recognize that some choice design is inevitable, (ii) nudging should be done transparently, (iii) rationales for nudging should be publicly accessible. (iv) revision procedures should be put in place.

OP78 Picturing ELSI+: Mapping Ethical, Legal, Social And Value Issues

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Introduction. Health technology assessment (HTA) is value-laden. Consideration of ethical, legal, and social issues (ELSI), and patient values (ELSI+), is challenged by lack of conceptual clarity and the multi-disciplinary nature of ELSI + . This study used concept mapping to identify key concepts in the ELSI+ domain and their interrelationships.

Methods. We conducted a scoping review using Medline and EMBASE (2000-2016, English language) with search terms related to ethics, legal/law, social/society/patient, "ELSI", and HTA/technology/assessment. Items from the review and additional items from an expert brainstorming session were consolidated into 80 ELSI +-related statements which were entered into Concept Systems® Global MAX software. Participants (N = 38; 36 percent researchers, 21 percent academics; 42 percent self-identified as HTA experts) sorted the statements into thematic groups that made sense to them, and rated the statements on their importance in decision-making about adoption of technologies in Canada: 1 (not at all important), 5 (extremely important), 2, 3, and 4 (unlabeled). We used Concept Systems® Global MAX software to create and analyze concept maps with four to 16 clusters, which were reviewed by the study team.

Results. We selected the map with five clusters because its clusters represented different concepts and the statements within each cluster represented the same concept. Based on the concepts, we named these clusters: patient preferences and experiences, patient quality of life and function, patient burden/harm, fairness, and organizational. The highest mean importance ratings were for the statements in the patient burden/harm (3.82) and organizational (3.92) clusters.

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