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

Bart Bloemen (bart.bloemen1@radboudumc.nl), Maarten Jansen, Wouter Rijke, Wija Oortwijn and Gert Vanderwilt

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

Michal Stanak (michal.stanak@hta.lbg.ac.at)

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

Murray Krahn, Karen Bremner (kbremner@uhnresearch.ca), Claire de Oliveira, Nisha Almeida, Fiona Clement, Diane Lorenzetti, Patricia O'Campo, Petros Pechlivanoglou and Andrea Tricco

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.

https://doi.org/10.1017/S026646231900134X Published online by Cambridge University Press

Conclusions. This study suggests an alternative approach to conceptualize the domains originally described as "ELSI+". We identified clusters of relevant concepts that focus on patient perspectives (preferences, experiences, quality of life, function), burden and harm, fairness (individual and societal), and organizational issues. Basing ELSI+ on conceptual consonance, rather than academic disciplines or traditions, provides a framework for coherent consideration of ELSI+ in HTA.

OP79 Improving Public Understanding Of Scottish Medicines Consortium Advice

Jennifer Dickson, Louise Taylor (louise.taylor51@nhs.net), Jackie McCormack, Noreen Downes, Lindsay Lockhart and Laura Walker

Introduction. Transparency of processes and decision making is important to the Scottish Medicines Consortium (SMC). An independent review of access to new medicines in Scotland in 2016 recommended that SMC should review its communication of decisions with a view to achieving greater transparency. SMC therefore began to develop plain English summaries of advice on each new medicine.

Methods. A multi-stakeholder approach was adopted to develop the summary documents, with patient groups involved. Firstly, a review of communications for the public from other HTA organizations was conducted. The public involvement team then held a workshop to find out what patient groups felt would be important to include when explaining SMC decisions to patients and the public. The process was also informed by reviewing examples of good practice from other parts of NHSScotland, including patient versions of Scottish Intercollegiate Guidelines Network (SIGN) clinical guidelines. Exemplar documents were then developed and feedback sought from the Public Involvement Network Advisory Group.

Results. A format was developed for the SMC 'Decision Explained' summaries consisting of a question and answer format for each medicine decision in a two page document. The summaries were piloted internally over a six month period, during which the development process and layout were finalized. Since September 2018 these summaries have been published on the website alongside the technical advice.

Conclusions. Partnership working between SMC and patient groups has helped to develop a new way of communicating SMC's decisions to patients and the public in a clear way, helping to improve transparency and understanding. Evaluation of the summaries will be undertaken from six months of publication.

OP80 Impact Of Patient Group Participation At Scottish Medicines Consortium Committee Meetings

Jennifer Dickson, Lindsay Lockhart, Louise Taylor (louise.taylor51@nhs.net), Jackie McCormack and Laura Walker

Introduction. The Scottish Medicines Consortium (SMC) encourages patient group (PG) representatives to participate in the decision-making committee meetings, answering questions from committee members and providing points of clarity throughout discussions if required. In a continuous improvement approach the process and the participant experience is continually evaluated to monitor impact and emerging themes.

Methods. The interactions between committee members and PG representatives are recorded in writing by the public involvement team to monitor the questions or points of clarity raised. These interactions were analyzed using thematic analysis to look for emerging themes. Following the meeting, PG representatives are invited to complete an online survey on their experience of working with SMC.

Results. From July 2017 to October 2018, 36 PG representatives have attended committee meetings for the discussion of their submission. Committee members asked 17 PG representatives to contribute. Key themes that have emerged to date include insight into the impact of living with the condition on quality of life and how a new medicine may affect this. Survey feedback has been positive with participants reporting that patient engagement has been strengthened, and that the patient voice is heard, valued and supports committee members in making fully informed decisions. PG representatives expressed a willingness to participate again. Feedback also highlighted that the preparatory support offered to PG representatives by the public involvement team is highly valued.

Conclusions. Patient group participation in committee meetings has been received positively by PG representatives. They report that discussions relating to quality of life impact of medicines on patients and carers better reflect the lived experience, enriching committee's deliberations. This demonstrates SMCs commitment to openness and transparency and has strengthened patient engagement in our processes.

OP81 Building Technical Capacity To Promote Patient Involvement In Health Technology Assessment

Ana Toledo-Chávarri (anatoledochavarri@sescs.es), Yolanda Triñanes Pego, Blanca Novella, Eva Reviriego, Paula Cantero-Muñoz, Patricia Gavin, Yolanda Alvarez-Perez, Lilisbeth Perestelo-Perez and Maria Jose Vicente-Edo

Introduction. In December 2017, a patient involvement (PI) Interest Group was created in the Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS) Annual conference. It started as a voluntary group of health technology assessment (HTA) methodologists interested in PI. The objective of the Group is to promote and facilitate PI in HTA. With the support of the Spanish Ministry of Health and the RedETS Council the Interest Group grew to at least one member for each of the eight RedETS regional agencies and units. It currently has 22 members. The PI Interest Group works in periodic online meetings and an annual offline meeting to establish a space for experiences exchange and reach

https://doi.org/10.1017/S026646231900134X Published online by Cambridge University Press