



Reconciling ethical and economic conceptions of value in health policy using the capabilities approach: A qualitative investigation of Non-Invasive Prenatal Testing

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ABSTRACT

When evaluating new morally complex health technologies, policy decision-makers consider a broad range of different evaluations, which may include the technology's clinical effectiveness, cost effectiveness, and social or ethical implications. This type of holistic assessment is challenging, because each of these evaluations may be grounded in different and potentially contradictory assumptions about the technology's value.

One such technology where evaluations conflict is Non-Invasive Prenatal Testing (NIPT). Cost-effectiveness evaluations of NIPT often assess NIPT's ability to deliver on goals (i.e. preventing the birth of children with disabilities) that social and ethical analyses suggest it should not have. Thus, cost effectiveness analyses frequently contradict social and ethical assessments of NIPT's value.

We use the case of NIPT to explore how economic evaluations using a capabilities approach may be able to capture a broader, more ethical view of the value of NIPT. The capabilities approach is an evaluative framework which bases wellbeing assessments on a person's abilities, rather than their expressed preferences. It is linked to extra-welfarist approaches in health economic assessment. Beginning with Nussbaum's capability framework, we conducted a directed qualitative content analysis of interview data collected in 2014 from 27 Canadian women with personal experience of NIPT. We found that eight of Nussbaum's ten capabilities related to options, states, or choices that women valued in the context of NIPT, and identified one new capability. Our findings suggest that women value NIPT for its ability to provide more and different choices in the prenatal care pathway, and that a capabilities approach can indeed capture the value of NIPT in a way that goes beyond measuring health outcomes of ambiguous social and ethical value. More broadly, the capabilities approach may serve to resolve contradictions between ethical and economic evaluations of health technologies, and contribute to extra-welfarist approaches in the assessment of morally complex health technologies.

1. Introduction

Non-invasive prenatal testing (NIPT) is a novel and morally challenging technology; one that raises ethical questions broader than NIPT itself, and evokes issues relevant to groups beyond those who interact with the technology directly (Hofmann, 2008). When making decisions about whether and how to implement this technology, policy decision-makers must consider a broad range of issues beyond clinical efficiency, including the technology's economic, social, and ethical implications. This holistic policy consideration is complex and value-laden, and sometimes results in conflicting assessments (Giacomini et al., 2013). For example, with NIPT, economic evaluations often rely on

assumptions that conflict with ethical analyses, resulting in assessments that raise ethical concerns about the technology's use. In this research, we propose a theoretical approach that may help ameliorate these issues. We use NIPT as a case study to explore whether the capabilities approach could be used to resolve contradictions between economic and ethical framings of 'value' for morally challenging health technologies.

1.1. Non-invasive prenatal testing

Non-invasive prenatal testing (NIPT) analyzes cell-free fetal DNA circulating in maternal blood in order to gain information about the

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fetal genotype (Hui and Bianchi, 2017). This technology became commercially available in the United States, Canada, and Western Europe as early as 2011, and is now available globally (Chandrakumar et al., 2014). In Canada, where this study takes place, NIPT was \$800–1000 CAD when first introduced (Vanstone et al., 2015a); and is currently available for approximately \$500 CAD (Nshimyumukiza et al., 2017). NIPT is currently used to detect trisomies 13, 18, 21, and sex chromosome abnormalities (ACOG, 2015), but it is likely that NIPT will eventually be expanded to include a variety of genetic conditions (Hui and Bianchi, 2017).

NIPT is unique among the array of prenatal screening technologies currently available because it can provide information about the fetal genotype as early as 9 weeks' gestation, with higher accuracy than existing screening tests and no risk of miscarriage (Vanstone et al., 2014). At this point, NIPT is still a screening test, and most clinical practice guidelines recommend that positive results be confirmed with invasive diagnostic tests (e.g. amniocentesis) which carry a small risk of miscarriage (ACOG, 2015).

NIPT has been rapidly and broadly adopted for prenatal genetic testing, as both a first-tier screening test for disability and as a second-tier screen to reduce the risk of iatrogenic miscarriage from invasive diagnostic procedures (Minear et al., 2015). This expansion has been facilitated by industry imperatives. NIPT technologies were developed by a number of different private companies, and in many places remain private-pay technologies, although some jurisdictions have recently offered coverage through public and private insurers (Minear et al., 2015; Vanstone et al., 2015b).

The commercial proliferation of NIPT preceded careful policy decision-making about its use and value (Vanstone et al., 2014). Evidence around NIPT's clinical utility for different conditions and patient populations is still developing, and it is not yet clear how NIPT will integrate with existing prenatal testing technologies (Murdoch et al., 2017). The rapid expansion of NIPT has raised ethical concerns about the routinization of testing and erosion of informed decision-making processes (Deans and Newson, 2012; Lewis et al., 2013). Like other prenatal testing technologies, NIPT is challenged by ambiguously defined social and medical purposes (Mahowald, 2007). Furthermore, ethical and policy analyses of NIPT are complicated because NIPT is not a homogeneous entity; it can refer to a number of slightly different methods for analyzing fetal genetic material, and is used by people and practitioners in different ways and for different purposes (Vanstone et al., 2015b).

1.2. Economic and ethical evaluations of NIPT

Policy evaluations of health technology rely heavily on a construction of the purpose of the technology. Novel, ill-defined, and morally challenging technologies like NIPT can pose a substantial challenge to policy decision-makers, because the technology's purpose may be conceptualized in different, sometimes contradictory ways (Giacomini et al., 2013).

In the case of NIPT, ethical and economic analyses suggest conflicting purposes. Ethical and social analyses usually suggest that NIPT's purpose should be to facilitate informed choice and reproductive autonomy (Deans and Newson, 2012; Dondorp and Lith, 2015; Jong and Wert, 2015). In contrast to this approach, cost-effectiveness analyses (CEAs) of NIPT tend to use outcome measures such as cost per additional chromosomal abnormality detected, cost per additional termination, and cost savings per disabled child not born. CEAs measuring health related quality of life (QALYs) usually measure only maternal QALYs, and include no loss of QALYs for fetuses that might have become babies with a genetic condition (Goldhaber-Fiebert and Brandeau, 2015). These outcome measures might have the normative effect of framing NIPT as a project that becomes more 'cost effective' (or worthwhile) only when it prevents a sufficient number of births affected by genetic disability. Members of the disability community have

raised serious ethical concerns about framing the purpose of prenatal testing technology in this way (Jong and Wert, 2015; Mahowald, 2007; Parens and Asch, 2000). Furthermore, the use of these outcome measures puts policy decision-makers in a challenging situation, because one component of an assessment of NIPT—the economic evaluation including CEA—is evaluating NIPT's ability to deliver on goals that another component—the social or ethical analysis—suggests it should not have.

This tension between clinical outcomes used in CEA or CUA and ethical or social analyses of how a technology should be used is not unique to NIPT. Morally challenging health technologies may often be evaluated for their cost-effectiveness in achieving clinical outcomes that are socially controversial or ethically problematic; for example, see the ethical arguments against framing pediatric cochlear implants as a technology to cure deafness as a 'disease' (Giacomini et al., 2013). However, there is no consensus, in method or theory, on ways in which economists might explicitly consider the ethical or social 'value' of a morally challenging health technology when choosing outcome measures for health economic assessment.

This discussion of value touches on a wider question, related to what can be included in the 'evaluative space' (Sen, 1993) of health economic assessments—in other words, what kind of information should be considered. Briefly and broadly, the classical answer is the 'welfarist approach': that the evaluative space in economic assessment should be limited to individual preferences, or 'utility'. However, much modern work in health economics has moved beyond a narrow focus on individual utility, towards an 'extra-welfarist' approach (Meltzer et al., 2016). Extra-welfarism does not limit its evaluative space to individual utility, and may include utility information but may also evaluate other outcomes, like states and characteristics, or weigh utilities from different populations differently. Extra-welfarism also considers stakeholders beyond directly affected individuals (Brouwer et al., 2008).

In health economics, extra-welfarist analyses typically focus solely on health outcomes (e.g. number of terminations, QALYs) (Coast et al., 2008b). However, as we have described, these may conflict with ethical assessments of NIPT. Many health policy decision-making organizations have explicitly adopted an extra-welfarist approach, or prioritized the inclusion of diverse stakeholder perspectives in their analyses (CADTH, 2017). This provides scope, both within extra-welfarist economic theory and within relevant evaluative bodies, for selecting outcome measures informed by ethical as well as social and individual conceptions of value.

In this paper, we provide a theoretical argument for making capabilities (Anand, 2005a; Nussbaum, 2003; Sen, 1993) the evaluative space for economic assessments of morally challenging technologies such as NIPT. Through qualitative analysis, we demonstrate that NIPT can be conceptualized and evaluated as a technology that affects the size, value, and richness of one's capability set. In doing so, we provide an example of how the capabilities approach may contribute to economic assessments of NIPT that can accommodate ethical and social perspectives on how these technologies ought to be used.

2. The capabilities approach and NIPT

The capabilities approach was developed by Amartya Sen as an alternative to standard utilitarian welfare economics (Sen, 1993), and was highly influential in the development of extra-welfarist approaches in health economics (Brouwer et al., 2008). Its central normative proposition is that wellbeing assessments should be based on "what people can do" (their capabilities) as opposed to "what they actually do" (their functionings) (Anand, 2005a p. 299). In practical terms, a person's 'capability set' is the set of things they realistically have the opportunity to achieve (Anand, 2005a; Sen, 1993; Sen, 2001).

Sen and other capability theorists have argued that welfarist economics is limited in its ability to assess wellbeing because it takes as its informational basis the amount of benefit or pleasure (utility) that

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