

Challenges of Consent in the Changing Prenatal Landscaping

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Who is asking for prenatal screening?

- We have an extremely limited understanding of what patients are looking for and under what circumstances.
- This gap in information sits in bold contrast to the steady expansion of prenatal testing.

Purpose of expanded prenatal screening?

- Population health gain?
- Facilitating and expanding autonomous reproductive choice?
- Primarily a “market driven” expansion of technology?

(These questions also apply to NIPT)

To facilitate and respect patient autonomous choice and consent test need “proportionality”

- Diagnostic tests should be adjusted to align with diagnostic questions.
- An acceptable test is one that lends more toward diagnostic related advantages than ambiguity and disadvantages.
- Test should be calibrated to the original diagnostic question.

Proportionality of tests?

- The use of wider tests marks a departure from the original diagnostic question; taking us into the domain of screening to identify any fetal abnormality.

New terrain.....

- Distinction between intended and incidental findings is rapidly becoming blurred in the emerging prenatal terrain between diagnostic test and screening tests.

Proportionality of tests?

- Larger sequencing marks a divergence from original clinical question to identify *any* fetal abnormality.

Clarity as to what is research

- Blurring between the boundaries of clinical care and research runs the risk of turning women into research subjects without their knowledge or consent (de Jong et al. 2014)
- Whole genome arrays are explorative by design and purpose.....(Bassem et al., 2006)

Maximum yield approach..

- Why withhold anything?
- Ethically it must be **demonstrated** as to how generating large amounts of uncertain information forwards a woman's reproductive choice.
- Women will chose what value they put on information and choices; but choices must be meaningful and tangible to represent an expression of autonomy.
- Maximum yield approach could impair autonomous choice.

Is this diagnostic or research

- Intermediate transition between research and full clinical application.
- Consent for research or for diagnostic criteria?

What should consent look like with prenatal testing?

- Virtually impossible to cover all conditions tested for with patients.
- Consent process will need to be collaborative and involve “tiered “ information retrieval options.
- Essentially providing categorized findings reflective of patients values, wishes, choice.

What do we need now?

- Better information of patient wishes.
- Capacity research and training to provide a more nuanced form of consent.

Creating Architecture

- We are at the foundational stage of what is to come.
- Wapner's findings (1.7%) will likely drive testing forward.
- Building capacity for excellent genetic counselling and consent process is critically important now, before further expansion.
- We must develop and adapt ethically grounded models of consent as we progress.