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**ESHG Symposium
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Array in daily practice

Ethical issues

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Aims

- different types of arrays
- different contexts of testing
- specify key moral questions/issues
→
- input for workshops/plenary meeting

Background: dynamics of genetic testing

Additional value of (targeted or WG) array

Clinical use of array

- testing in affected pregnancies/pregn. at > risk
- postnatal (differential) diagnostics

Routine offer of array: *(prenatal) screening?*

From (WG) arrays to WGS/WGA: cheap and affordable?

The Holy Grail: personalised (reproductive) medicine for all

General ethical principles

Beneficence and non-maleficence, also towards *relatives*

Respect for autonomy, including the *child's* future autonomy

Privacy

Justice

How to interpret and apply these principles?

First things first: preventive ethics

Array designs

- Targeted: maximize coverage of relevant sections of the genome, minimize findings of UCS
- WG: maximize

What is to be preferred – and who decides?

In the context of PND: targeted (Savage et al., 2011)

But: what about patient preferences/individualized choice?

Array in clinical practice: *'unexpected' findings*

Nomenclature

Not new, but > frequency

Types of UFs: focus on pathogenic CNVs:
to tell or not to tell?

The right (not) to know → informed consent, but ...

whose interests/rights are at stake (children?), and

how to balance these, *how to handle conflicts*

in *pre-* and *postnatal* testing?

'Unexpected findings': some moral conflicts

1. Prenatal

- minor disease: controversial/don't tell: 'TOP only if serious disorder'?
But what about reproductive autonomy?
- untreatable late-onset disorder: 'controversial' (Zuffardi et al, 2010) But why? Not serious? Avoid 'double bad news' (WFN, 1994)? The future child's right not to know? (De Wert, 2002)

2. Postnatal

A. Adult

- late-onset disease: 'controversial'
Again: why? (Un-)justified paternalism?

B. Child:

- untreatable late-onset disorder: parental authority or the child's right not to know?
- treatable childhood disorder: parental authority or the best interests of the child/the child's right to know?

Array in clinical practice: *generic* consent?

Traditional informed consent: linked with respect for autonomy. Desirable and feasible?

An alternative: generic consent, just general information.

- advantages: avoid info-overload, fast and cheap;
→ example of how this might be done
- risk: a violation of the right not to know, at odds with the principle of non-maleficence

The challenge: generic consent, but still *sufficiently informed*

Array in clinical practice: re-contacting?

Pros and cons?

Conditions for recontacting?

- only if there is a medical advantage?
- only if there is a link to orig. problem/question for help?
- only if there still is a professional relation?
- other?

When, if ever, is there *a duty* to recontact?

Blurring boundaries

(WG) array in the context of diagnosis:
diagnosis or *screening*?

Why is this a relevant question?

Proportionality matters

Prenatal microarray screening?

What are the ethical issues? (Shuster)

- informed consent ...?
- > false-positive test results
- > anxiety
- *de facto* a roadblock for life (*is it??*)

Plus: blurring the distinction between newborn profiling and prenatal screening

WG array screening is like WGS

What is the aim of prenatal screening?

Conclusions

- Ethical guidance reg. arrays is urgently needed
- The basic issue regards the selection of the appropriate array design; does one size fits all?
- Generic consent seems to be unavoidable; the vexing question is how it should be designed
- Issues related to UF's and the right (not) to know can only be adequately addressed if one takes account of the rights and interests of all parties involved, incl. (future) children