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NEGOTIATING INTERESTS: REVISITING THE ROLE OF CONSENT IN NEWBORN GENETIC SCREENING

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Context and acknowledgement

- Newborn Screening (NBS)
 - Bloodspot screening
- New tests:
 - Tandem mass spectrometry of biochemical markers
 - DNA extraction and analysis
 - Pressure to expand
- Parental proxy consent
- Ordinary vs extraordinary times
- Acknowledgement:
Professor Roger Brownsword (KCL)

Structure

1. Original aims and rationales of NBS
2. Proxy consent: ideal typical model
3. Contemporary NBS models
4. Decision-making in expansionary mode
5. Legitimate interests
6. Challenges, negotiating interests and deviation.

Aims and rationales of screening

- Wilson and Junger, *Principles and practice of screening for disease* (1968):
 - Set a high bar for screening: conditions should be important and treatable; screening needs to be effective and acceptable;
 - Does not speak to genetic screening;
 - Does not say screening programmes should be based on informed consent/ proxy consent of parents (P) where children concerned.

Aims and rationales of NBS

‘to detect newborns with serious treatable disorders to facilitate appropriate interventions to avoid or ameliorate adverse outcomes. The condition sought should be an important health problem and there should be an accepted treatment for patients with recognized disease as well as availability of facilities for diagnosis and treatment. The condition to be screened must be severe, frequent, and amenable to easy, safe, reliable, and inexpensive laboratory diagnosis on a very large scale’ (FIGO 2009)

- Screening contexts: clinical medicine, public health programmes, direct-to-consumer services.
- Symptomatic and asymptomatic populations.
- Screening for benefit of others (research, family members, future children etc).
- Expansion to untreatable/ asymptomatic conditions?
- Complex assessment of benefit and harm.

Proxy Consent

- By necessity, children need others to make decisions on their behalf.
- Governance of the relationship between parents (acting on their behalf) and HCPs can be difficult.
- Starting point: rights based regulatory regime:
 - rights-holders may alter their position vis duty-holders
 - Justificatory function of consent: does not suffice to show that an action is right BUT prevents a complaint by consenting party that their has been a violation of rights.
 - Assumption: consent by P (as proxy for N), should shield H from complaint by P and N.
 - The possibility of overriding justification is recognised BUT only where H has a conflicting higher ranking right.

Ideal Typical Proxy Consent Model

Parents have a veto and consent is taken seriously as justification for action.

Conditions:

1. Consent by parents as a necessary and sufficient justifying condition for the proposed action. (no consent: prima facie violation).
2. Parents' consent is to be treated as valid only where (a) explicit and clearly signalled; (b) freely given; (c) informed.

Parental consent should (ideally) flow from a relational process.

Scope of parental consent/veto

- Extent to which interests of child and others might constrain parental rights.
- Different interpretative approaches where consent is being given/ withheld on behalf of another?
- Pressure points - circumstantial factors:
 - In ordinary times: appeals to professional duty/ optimisation of health to child/ community.
 - In extraordinary times: appeals to responsibility/ solidarity/ states of exception.

Deviations and pressure

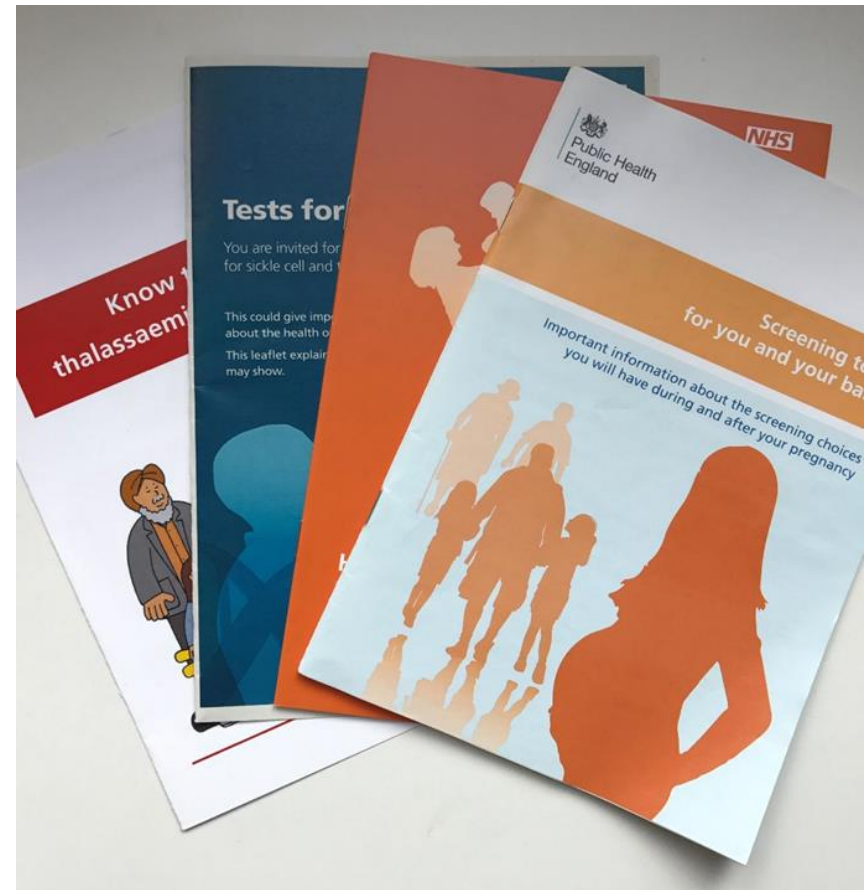
- Ways in which pressure might be applied to the ideal typical model:
 - **De-centring** consent as a necessary and sufficient condition for justified action (condition 1);
 - **Diluting** the particular requirements of valid consent (condition 2).
 - **Displacement** of the rights-based paradigm;
 - **Downgrading** the importance attached to/ scope of a particular right;
- Attacks on consent might mask the real target (the rights regime).
- Dilution might mean that HCPs use consent simply as the means to legitimise their actions.

Contemporary NBS models

- A. **Mandatory**
 - B. **Opt-out (screening as the norm)**
 - C. **Opt-in**
- The lines between these models can be blurred but in model A: consent/ rights are not taken seriously
 - It is easy to see how model B might de-centre and dilute consent in practice.

NBS Example: England

- Promotes model C (opt-in).
- Verbal/ single parent proxy consent process.
- Discussion in 3T and shortly after birth (supported by informational leaflet).
- Bloodspot screening for 9 conditions: some choice over testing/ report options.
- Proxy consent recorded in newborn records.
- Additional written formalities where parental veto exercised.
- Default 5 year+ storage and use for quality improvement/ research
- Testing presented as *responsible parenting*.
- Evidence suggests **dilution** of consent may occur in practice and differential views depending on reason for testing (Ulph et al. (2020)).
- Closer to an 'opt-out' model in practice.



Decision-making in expansionary mode

- Expression of gene variation is shaped by a range of internal/external factors, making whole exome or genome results difficult to interpret.
- Expansion may mean:
 - Individual benefits becomes more diffuse/ remote and less compelling;
 - Effective consent processes become more difficult as complexity of choices/ informational requirements change (Botkin 2017).
- The most likely deviation may be to regimes that pay lip service to opt-in.

Decision-making in expansionary mode

- Range of decision-making:
 - Decisions as to the **scope**;
 - Decisions to **test**;
 - Decisions as to **reporting**;
 - Decisions as to **data retention and storage**;
 - Decisions as to **research/ later use**.
- Interests, consent processes and inclusion criteria may differ at each point.
- The demands of condition 2 (especially informational) are likely to be problematic during periods of expansion.
- Blanket models of consent may not be helpful:
 - Breaking down decision-making/ consent processes into separate components (pros/cons).
 - Or stratified informational processes based on parental want.

Legitimate interests and the scope of parental rights

- Are parental rights based on direct interests, or derivative from the interests of the child?
 - Lord Scarman in Gillick [1986]: *'[parental power and control] exists primarily to enable the parent to discharge his duty of maintenance, protection, and education until he reaches such an age as to be able to look after himself and make his own decisions'*
 - The problem of 'open futures' (Feinberg (1992))
- Framing parental consent in duty terms and as necessary to the extent that it serves present or future interests of the child, offers a platform to circumvent condition 1.
- Oviedo Convention/ Additional Protocol – most interventions require direct benefit for the test subject or very tight regulatory constraints.
- State actors/ HCPs need to balance interests: there are reasons (beyond rights) why condition 2 should be taken seriously: maintenance of trust in NBS and avoidance of legal disputes.

Challenges

1. New genetic tests create opportunities and challenges for the governance of NBS.
2. Mapping/ classifying NBS regimes against the 'ideal' typical consent model may be problematic:
 - the gap between promise and reality;
 - multiple decision-making elements;
3. Even if the sovereignty of consent is not questioned, implementation of the ideal typical model will be a major challenge.
4. The possible pressure points do not tell from which ethical constituency the pressure will be applied or the specific form it will take.

Negotiating interests and deviation?

- Need to think carefully about higher ranking (overriding) rights.
- If we negotiate/ vary conditions of consent, can we be sure these variations will be respected in practice?

Closing remarks

- Pressure to expand may come from obvious challenges (utilitarian, paternalistic or communitarian ethics)
- BUT important we do justice to any model of consent used.
- Expansion of NBS in ordinary times is one thing.
- In extraordinary times, neither rights nor consent may be a focal consideration.