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In ordinary times, in extraordinary times: Consent, newborn screening, genetics and pandemics

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ABSTRACT: Against the backdrop of newborn genetic screening and pandemics, this article examines disputes between parents, acting as proxies for their children, and healthcare professionals. While some will support parents, others will push-back against proxy consent and the right to veto actions that are proposed by the professionals. Whereas in ordinary times, such a push-back might seek to displace or downgrade parental rights (e.g. by appealing to professional duty or the optimisation of health) or to de-centre or dilute consent, in extraordinary times, rights and consent are superseded by appeals to responsibility, solidarity, and even "states of exception".

KEYWORDS: Proxy consent; newborn screening; genetic screening; stewardship; extraordinary times

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1. Introduction

Governance of the relationship between parents, acting on behalf of their children, and healthcare professionals, can be challenging; and, as is well-known, particular disputes can be emotionally charged and protracted.[1] While some will support the rights of parents, others will push-back against parents having the right to veto actions that are judged by the professionals to be either in the interests of the child or in the general interest. Whereas, in what we will call *ordinary* times, those who challenge parental rights and consent might appeal to, say, professional duty and to the optimisation of the health and well-being of the child, in *extraordinary* times, these familiar appeals are superseded by appeals to responsibility and solidarity, to unprecedented circumstances, and even to the dangerous idea of "states of exception".[2]

With a view to clarifying the nature of such contestation around parental rights and consent, our discussion is in three principal parts. First, we sketch our thinking about consent in general and proxy consent in particular. At the heart of this thinking is an "ideal-typical" model of proxy consent, set in a rights-focused regulatory context. This model provides a benchmark not only for mapping where particular regimes of medical law and public health law stand (both on paper and in practice) but also for highlighting four key ways in which pressure might be applied to the model: namely, with a view to *displacing* the rights-based paradigm within which consent plays its distinctive role, to *downgrading* the importance attached to, or the scope of, a particular right, to *de-centring* consent as a necessary and sufficient condition for justified action, or to *diluting* the particular requirements for a valid consent.

Secondly, assuming ordinary times and the typical pattern of contestation in biolaw and bioethics, we focus on newborn screening (NBS) programmes, some of which treat screening as mandatory (displacing both rights and consent), some of which operate with opt-out consent (diluting the signalling requirements for consent), and some of which (in line with our model) require a parental consent by opt-in. In the context of proposals to extend NBS so that more genetic data is obtained,[3] we seek to clarify the challenges to regimes of rights and, concomitantly, to our model of consent – not only the obvious challenges presented by the ethical approaches (whether utilitarian, paternalistic, or communitarian) that underlie regimes that are mandatory but also the challenges for

[1] Famously, see the case of Charlotte Wyatt and the Nuffield Council on Bioethics, *Critical care decisions in fetal and neonatal medicine: ethical issues* (London, November 2006). Recent examples are the cases of Charlie Gard and Alfie Evans, on the former of which see, e.g., E. CAVE, E. NOTTINGHAM, *Who Knows Best (Interests)? The Case of Charlie Gard, in Medical Law Review,* 26, 2018, 500; and J. MONTGOMERY, *The "tragedy" of Charlie Gard: a case study for regulation of innovation*, in *Law, Innovation and Technology,* 11, 2019, 155.

[2] On which, see A. SUPIOT, *The Return of "Rule by Men",* in ID., *Governance by Numbers*, Oxford, 2017, (trans Saskia Brown).

[3] For assessment, see, e.g, B.A. TARINI, A.J. GOLDENBERG, *Ethical Issues with Newborn Screening in the Genomics Era,* in *Annual Review of Genomics and Human Genetics*, 13, 2012, 381; and, S. TAYLOR-PHILLIPS et al., *The Ethical, Social and Legal Issues with Expanding the Newborn Blood Spot Test,* Warwick, 2014, (on file with authors). On the potential of extending NBS, see, UK National Screening Committee, *Generation genome and the opportunities for screening programmes*, 2019, 18-19, available at: https://bit.ly/3aLDztR (last accessed October 11, 2020); and HM Government, *Genome UK: The future of healthcare*, September 2020, 27-28, available at: https://www.gov.uk/government/publications/genome-uk-the-future-of-healthcare (last accessed October 11, 2020).

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rights theorists of doing justice to the model of consent as well as ensuring that parental rights are not abused.

Thirdly, assuming extraordinary times, we consider disputes between parents and healthcare professionals with particular reference to public health interventions in the context of a pandemic (for example, concerning the vaccination of children or their participation in a research study to identify relevant genetic markers). Resisting the framing of such disputes in a way that treats extraordinary times as a state of exception (giving professionals a carte blanche), or as an extension of ordinary times arguments (but with utilitarian and duty-based arguments for solidarity now having the upper hand as against rights-based arguments and individual consent), we argue for a quite different understanding of the issues raised by extraordinary times considerations. Crucially, we argue that our best understanding of concerns about responsibility and solidarity is that ordinary time justifications are superseded in extraordinary times by the urgent need to take steps to restore and maintain the global commons (the pre-conditions for the existence of any kind of human community with any kind of guiding ethical perspective). Accordingly, even for a community that, in ordinary times, takes both rights and consent seriously, in extraordinary times, it will be the stewardship responsibilities relating to the global commons that supply the overriding reasons for action.

Finally, in some short concluding remarks, we indicate some of the further questions that are invited by, and the implications to be drawn from, our analysis.

2. Consent and Proxy Consent

Before sketching an ideal-typical model of proxy consent, that model itself needs to be placed within the context of a distinctively rights-based regime of rules and standards. Accordingly, we start with some prefatory remarks about such a regime and the justificatory function of consent within it before setting out our ideal-typical model of proxy consent and the principal pathways to deviation from it.[4]

2.1. The paradigm of a rights-based rule regime

The paradigmatic setting for consent is a rights-based regime of rules and standards (legal or moral) that regulates the interactions and transactions between individual agents as well as the relationship between citizens and public bodies. In such a regime, individuals have claim rights (that some other individual or individuals should or should not do x); and, it follows that those latter individuals have a correlative duty to do, or not to do, x.

The function of consent is both dynamic and justificatory. Consent is dynamic in the sense that it enables rights-holders to alter their position in relation to duty-bearers by waiving the *benefit* of a right although not the *right* itself; and, consent is justificatory in the sense that it authorises an act that would otherwise violate a right. However, consent does not suffice to show that an action is right as such; rather, it suffices to prevent a complaint (by the consenting party) that an action involves a violation of the consenting party's rights. Hence, where A consents to some action, x, by B,

[4] In this part of the article, we draw on D. BEYLEVELD, R. BROWNSWORD, *Consent in the Law,* Oxford, 2007.

then the function of that consent is to authorise B to do x and, at the same time, to preclude a complaint by A that B thereby violates A's right that x not be done. However, A is the only party so precluded – or, at any rate, this is the case unless A is acting as an agent or as a proxy for others. So, for example, if B's doing x is a prima-facie wrong relative to Z, the fact that A has consented to B doing x is no answer to Z. Where A is acting as a proxy, a similar analysis applies. Thus, where A, in consenting to some action, x, by B is doing so as a proxy for C, we take it that A's consent precludes a complaint by both A and C that B has done wrong by doing x. In both cases, consent serves, as Lord Donaldson famously expressed it, as a flak-jacket for B, but the cover that it provides for B is limited to the consenting parties.[5]

Turning this round, if B goes ahead and does x (which is covered by A's right) without having obtained A's consent (indeed, where A has explicitly declined to give consent), then B seems to have no answer to A's complaint that B has infringed A's right. So far, so straightforward. However, in a rights-based regime, B might concede that doing x does involve a violation of A's right (which, moreover, is a matter for regret) but that the doing of x is justified all things considered because it serves a higher ranking right than the right violated.

This formal analysis leaves much still to be settled. For example, there are important questions about the rights-based regime itself, about the substance and scope of particular rights, about how conflicting rights are ranked and prioritised, and so on; and it might fairly be said that, if parental rights are to be privileged and if their consent is to be protected by stringent requirements, we really need to understand why such importance is attached to these particular interests. These are matters to which we will return in the next part of the article.

2.2. An ideal-typical model of consent by proxy

In principle, there are many models of consent – broad and narrow, opt-in or opt-out, static and dynamic, relational and non-relational, and so on.[6] For the purposes of anchoring our discussion, and providing a benchmark for various regimes of proxy consent, we will sketch an ideal-typical model of consent by parental proxy – that is, a model where parents have a veto and where their consent is taken seriously as the justifying reason for whatever action, x, is proposed in relation to their baby (such as drawing, analysing and storing a baby's blood).[7]

Bearing in mind that our model is placed in the setting of a rights-based regime of rules, and assuming that there are no doubts about the capacity of the parties, the central features or conditions of the ideal-type are as follows:

[5] See, *Re W (A Minor) (Medical Treatment: Court's Jurisdiction)* [1993] Fam 64.

[6] See, e.g., R. Brownsword, *Regulating Biobanks: Another Triple Bottom Line*, in G. Pascuzzi, U. Izzo, M. Macilotti (eds), *Comparative Issues in the Governance of Research Biobanks,* Heidelberg, 2013, 41; J. Kaye, E.A. Whitley, D. Lund, M. Morrison, H. Teare, K. Melham, *Dynamic consent: a patient interface for twenty-first century research networks*, in *European Journal of Human Genetics,* 23, 2015, 141; and I. Budin-Ljøsne et al., *Dynamic Consent: a potential solution to some of the challenges of modern biomedical research*, *BMC Medical Ethics,* 18, 2017, available at: https://bit.ly/2RNFwPv, doi: 10.1186/s12910-016-0162-9.

[7] Nb, although we are presenting this model as an "ideal-type", we are not claiming that this approach to consent is "ideal", merely that it is a robust representation of the view that the consent of the parents really matters.

- Consent by the parents is viewed as the necessary and sufficient justifying condition for the proposed action, x; and, as a corollary, where parents either decline to give their consent, or simply do not give their consent, then doing x will involve a violation of the parents' prima facie rights.
- The parents' consent is to be treated as valid only where it is (a) explicit and clearly signalled, (b) freely given and (c) informed; and,
- The consent of the parents should, at least as a matter of aspiration, flow from a relational process.

The significance of the first condition – the sovereignty of consent – is that those who take action x have one, and only one justifying answer to the parents (and to the baby or child on whose behalf the parents act as proxy) where it is claimed (and conceded) that action x involves a violation of the parties' rights. That answer is that the parents consented to x. It is no answer, for example, to appeal to professional duty or social utility. Of course, as we have already flagged up, within the rights-based paradigm, the violation of the parties' rights might be admitted but an all things considered justification might be put forward. So, we need to be careful about how we express the sovereignty of consent. In a rights-based regime, consent is the necessary and sufficient justification for an act that involves a prima facie violation of a right but that (wrongful) act might still be justified by appealing to a more compelling right. The significance of the second condition only becomes apparent when we spell out the demanding nature of the specification of a valid consent. In other words, it is only when we specify that the signalling of consent must be unequivocal, that the circumstances in which consent is given must be free of undue or improper pressure, and that being informed is not satisfied merely by the absence of misinformation, that we grasp that the ideal-typical model permits no short cuts to a valid consent. As for the third condition, although this is aspirational and does recognise some practical limitations, it clearly views consent as more than a singular event. No doubt, the term "consent" is often used to denote a specific transaction between stakeholders or to fix the particular moment when A authorises B to do x (thereby exercising a power to transform B's duty not to do x into an immunity where x is done).[8] However, in practice, to the extent that this mode of thinking tends to encourage a perfunctory approach to consent, it needs to be adopted with care.

Finally, two other points, should be noted. One point is that it is one thing for a person to give or to withhold consent purely on their own behalf and quite another thing for parents acting as a proxy for their baby or child to give or withhold their consent. In the former case, it is simply the interests of the person that are relevant – and, indeed, we might say that their decision to give or to withhold consent, no matter how irrational or unreasonable it might seem, is to be respected.[9] By contrast, if a parental decision to give or to withhold their proxy consent seems to be irrational or unreasonable relative to the (clearly relevant) interests of the baby or child, then we are likely to take a very

[8] Compare W.N. HOHFELD, *Fundamental Legal Conceptions*, New Haven, 1964.

[9] As Lord Donaldson MR put it in *Re T (adult: refusal of medical treatment)* [1992] 4 All ER 649, 663: "the patient's right of choice exists whether the reasons for making that choice are rational, irrational, unknown or even non-existent. That his choice is contrary to what is to be expected of the vast majority of adults is only relevant if there are other reasons for doubting his capacity to decide".

different view of whether this is within the scope of the parental rights or whether it should be respected. The question of how the interests of the child might constrain parental rights is a matter to which we will return in section 3.4. The other point is that the distinction between persons consenting on their own behalf and parents consenting as proxies might be relevant in the event of there being some doubt about how to interpret the scope and breadth of the consent that is given. Arguably, in cases of doubt, the default should be a restrictive approach; but, where we are dealing with parents consenting as proxies, a contextual reading might be more appropriate. In practice, this point of interpretation might be an important one and it merits further consideration than we can give it here.

2.3. Four deviations from the ideal-typical model

Where there is pressure on parents to give their consent to action x, there is more than one pathway to deviation from the ideal-type. The four principal pathways are: displacement, downgrading, de-centring, and dilution.

First, pressure might be applied directly or indirectly (via consent) to *displace* the rights paradigm itself. Instead of rights, it might be argued, for example, that actions should be justified by reference to the duties and responsibilities that individuals have (to themselves and to others), or by some desirable consequences such as the maximisation of utility, or the minimisation of distress, or by the reduction of inequality, and so on.

Secondly, pressure might be applied directly or indirectly (via consent) with a view to *downgrading* the scope or significance of a particular right. In principle, this is quite different to arguing for the displacement of the rights paradigm; but, in practice, the flattening or narrowing of a particular right might be part of a more general ambition to challenge the rights paradigm.

Thirdly, in relation to the first condition of our model, pressure might be applied with a view to *de-centring* consent. Here, the argument would be that consent by the parents might be treated as sufficient but not strictly necessary – in just the way, for example, that, in some data protection regimes, the consent of data subjects to the processing of their personal data is a sufficient but not a necessary condition for lawful processing.[10] It follows that, even if the parents have not given their consent to the doing of x, the doing of x might not be viewed as any kind of wrong. Consent becomes simply one justifying option; and, the withholding of consent is no longer a serious blockage.

Fourthly, pressure might be applied to the second condition of our model with a view to *diluting* the requirements for a valid consent (or, possibly, as a strategy to displace or downgrade rights in practice). For example, there might be pressure to amend the specification so that implicit and indistinct signalling will suffice (as in opt-out models of consent); or it might be the requirement of freely given consent that is diluted; or the pressure point might be the informational requirement.

Of these four deviations, it is displacement that goes for the jugular. Sometimes, the seriousness of the challenge might be masked because the point of attack seems to be on consent itself; but, on closer analysis, we see that it is the rights-based regime that is actually the target.[11] Conversely, we

[10] Cf. the UK Data Protection Act, 2018.

[11] Compare, R. BROWNSWORD, *Rights, Responsibility and Stewardship: Beyond Consent,* in H. WIDDOWS, C. MULLEN (eds), *The Governance of Genetic Information: Who Decides?*, Cambridge, 2009, 99.

might think that dilution is the least threatening challenge. However, in practice, relaxation of the conditions for a valid consent can mean that those who seek consent are pushing at an open door. What we end up with then is a regime that pays lip service to both rights and consent but which actually has a quite different orientation. Once the specification of a valid consent is weakened in these ways, we might find that consent, far from protecting the interests of the intended party, becomes a convenient way for medical professionals or healthcare researchers to "legitimate" their actions. Ultimately, advocates of a proxy consent framework need to be alert to the full spectrum of challenges, both to the underlying rights paradigm and to the particulars of consent.[12]

3. In Ordinary Times: Proxy Consent and Newborn Genetic Screening

In this part of the article we discuss ordinary time debates about the extension of NBS programmes (in order to capture more genetic data). Our particular interest is both in mapping where regimes stand relative to our model of consent and understanding how regimes that are publicly committed to consent can be put under pressure to defect from those commitments.

Our discussion proceeds in four stages as follows: (i) we sketch the typical pattern of debates and disputes in modern biolaw and bioethics, where rights-based approaches are confronted by a plurality of rival approaches each of which, in its own way, challenges the importance and significance attached to consent; (ii) we distinguish between three models of NBS programmes – mandatory, opt-out, and opt-in, the latter two of which purport to rest, to a greater or lesser degree, on the sovereignty of consent; (iii) we consider the range and potential complexity of decisions to be made by the parents where NBS extends the genetic data collected; and (iv) we consider the legitimate scope of the rights of parents in making decisions as proxies for their children.

3.1. The pattern of debates in biolaw and bioethics

It was more than 50 years ago that Wilson and Jungner identified ten core principles for screening programmes.[13] Three aspects of their seminal statement are striking. First, the principles set a high bar for investment in screening – not only should the conditions screened for be important and treatable, screening for those conditions needs to be effective and acceptable. Secondly, and not surprisingly, the principles do not speak to genetic screening. Thirdly, perhaps a little more surprisingly, the principles do not say that screening programmes should be based on informed consent, let alone the proxy consent of parents where children are screened[14]. While these principles

[12] Compare, ID., *Consent in Data Protection Law: Privacy, Fair Processing, and Confidentiality,* in S. GUTWIRTH, Y. POULLET, P. DE HERT, C. DE TERWANGNE, S. NOUWT (eds), *Reinventing Data Protection?*, Dordrecht, 2009, 83.

[13] J.M.G. WILSON, G. JUNGNER, *Principles and practice of screening for disease,* Geneva, 1968.

[14] That said, it might be argued that (i) because we are discussing population-wide screening programmes rather than individual testing, we are already in the realm of public health, from which it follows (ii) that this is a matter for judgments about the public good rather than private right (and consent). However, quite apart from any difficulty in differentiating between screening and testing, the second part of the argument clearly begs the question. The fact that decisions are being made for the public good or in the public interest does not mean that individual rights are no longer relevant. See further 3.4.2.

have been refined and added to,[15] the culture of screening is still relatively cautious which suggests that advocates of expanded NBS, before engaging with the larger community, would first have to persuade the screening community that the proposal makes sense. How might the arguments go?

The pattern of debates in ordinary time biolaw and bioethics often has the following shape. The general direction of travel is towards recognising the centrality of individual rights (rights of patients and research participants) and the importance of informed consent. However, a rights-based ethic (with our ideal-typical model of consent) finds itself challenged by utilitarians (who regard consent as a transaction cost to be minimised in the pursuit of general benefit), paternalists (who believe that they should be the judges of the best interests of others) and conservative dignitarians (who deny the relevance of both rights and consent). While there might be some convergence between these approaches, there is a standing tension between them.[16] It also should be said that, within each ethical "camp", there will often be significant differences (both as to the relevant principles and as to their application to particular cases). For example, amongst utilitarians there might be different assessments of the likely benefits and harms resulting from an extension of NBS; and, while some dignitarians will be communitarians, others will be Kantians, and yet others will be relying on the doctrinal teaching of the Catholic Church.

This thumbnail sketch does not suffice to predict exactly how debates about the extension of NBS will go in any particular community. However, we might expect a degree of convergence between the positions taken by utilitarian and rights-based ethicists – at any rate, to the extent that there is a shared interest in making more actionable information available to parents. For utilitarians, this is a net benefit; and, for rights-theorists, it is in line with recognising parental autonomy (possibly articulated in terms of a right to know). Nevertheless, the convergence is far from complete. For those who take consent seriously, the information must be at the option of the parents; it is their choice whether or not to sign up for the extended NBS. So, when the extension of NBS is proposed, rights-based ethicists might give it their qualified support, their emphatic caveat being that parents should continue to be in a position to say yes or no on a free and informed basis.

By contrast, some paternalists might argue that it is not in the best interests of either parents or their children to have this kind of information; and, while some dignitarians might support a mandatory screening programme (as a matter of solidarity within the community), they might oppose the further "geneticization" of society on the grounds that it compromises human dignity. Given this pattern, it will be paternalists and dignitarians who seek to displace or downgrade parental rights and it will be utilitarians who, to the extent that they are persuaded that an extension of NBS will be beneficial, focus primarily on the displacement or dilution of parental consent.

[15] A. ANDERMANN, I. BLANCQUAERT, S. BEAUCHAMP, V. DÉRY, *Revisiting Wilson and Jungner in the genomic age: a review of screening criteria over the past 40 years,* available at: https://www.who.int/bulletin/volumes/86/4/07-050112/en/ (last accessed April 29, 2020).

[16] Compare R. BROWNSWORD, *Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the "Dignitarian Alliance",* in *University of Notre Dame Journal of Law, Ethics and Public Policy* , 17, 2003, 15; and ID., *Rights, Regulation and the Technological Revolution,* Oxford, 2008.

3.2. Contemporary models

NBS programmes might be placed in one of three categories: (i) where screening is mandatory; (ii) where screening is "normal" (or "advised") but subject to opt-out; and (iii) where screening is by opt-in.

In principle, the distinction between regimes that require consent and those that do not should be clear, as should the distinction between consent-based regimes that require opt-in and those that treat opt-out as sufficient. However, in practice, the lines between these different regimes can become blurred. Not only does this make categorisation more difficult, it can obscure the significance of the headline distinctions. Whereas, in principle, the distinction between mandatory regimes (where neither rights nor consent are taken seriously) and non-mandatory regimes (where parental refusal to NBS is determinative) is of capital importance, the difference between *opt-in* and *opt-out* models might seem to be a matter of detail. However, opt-out, rather than opt-in, might already reflect some dilution of the requirements for a valid consent and, indeed, the practical reality might be that, de facto, NBS is as good as mandatory.

Bearing in mind these cautionary remarks, we can speak briefly to each of the three models before conducting an initial stock-taking of how this bears on a proposed extension of NBS programmes.

3.2.1. Mandatory models

On the face of it, by requiring NBS, mandatory models displace parental rights and their proxy consent.[17] As FIGO (the International Federation of Gynecology and Obstetrics, and the self-proclaimed global voice for women's health) has put it: "in view of the fact that the overall acceptability of NBS is beyond doubt, NBS should be mandatory and free of charge if early diagnosis and treatment will benefit the newborn".[18]

Precisely which ethic supports this position is open to interpretation: as stated, it is in line with utilitarian thinking but it could be read as a paternalistic or even a communitarian stance that infers that parents do not have a legitimate or sufficient priority interest in the screening process. In many cases, though, this position is qualified by a State obligation to make relevant information available to parents, and by the need for separate written consent for other uses (including retention for research).[19] Not only does this highlight a distinction between obtaining up front agreement to testing/reporting, and agreement to the subsequent retention and use of samples/data, it foreshadows the potential complexity of mapping NBS regimes by reference to the role of consent.

[17] However, in some mandatory regimes (such as those operating in some US States) there will be a "conscientious objection" clause that permits parents to opt-out. See, B.A. TARINI, A.J. GOLDENBERG, *op.cit.*; and, J.R. BOTKIN, *Ethical Issues in Newborn Screening*, in L. FRANCIS (ed), *The Oxford Handbook of Reproductive Ethics*, Oxford, 2017, 251.

[18] Figo Committee Report, *Ethical aspects concerning neonatal screening FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health*, in *International Journal of Gynecology and Obstetrics*, 106, 2009, 273-274. However, while it might be "beyond doubt" that NBS is acceptable in the established cases, it is surely an over-statement if whole genome or exome screening is to be added.

[19] *Ibid*.

3.2.2. Opt-out models

In opt-out models, parents are nudged towards NBS. State actors often endorse or promote NBS, with parents retaining an option or choice not to test. Although there is implicit recognition that the parents have a legitimate interest in the process, screening is the norm. Parents bear the primary burden because they need to take active steps to exercise the option not to screen. The degree of burden may vary and opt-outs may be especially demanding if complex bureaucratic and explanatory mechanisms are put in place. Moreover, these already sticky nudges might be compounded by over-enthusiastic promotion by health care professionals, "hectic" environments,[20] tired parents, variability in comprehension and discretionary action by healthcare professionals, all making these models vulnerable to failure, especially in expanded frameworks with multiple conditions and options. Accordingly, while an opt-out model might purport to take parental rights and proxy consent seriously, in practice, it is all too easy to see how such a regime might both de-centre and dilute consent.

3.2.3. Opt-in models

Where opt-in models are adopted, nothing short of explicit, clearly signalled, free and informed proxy consent that covers all stages – including testing, the return of findings, subsequent use and storage – should suffice. All conditions in our ideal-typical model need to be met if we are serious about demonstrating that parents not only have a legitimate, but also an essential interest in screening. That said, in cases of parental conflict or indecision, there might be some nice questions about whether both parents must consent or agree to withhold consent. There may also be cases where parental consent is not available or where the State judges that there are "good" (compelling rights') reasons to override the parental position.

England promotes an "opt-in" model for NBS using a verbal only and single parent proxy consent process, supported by an informational leaflet and initial discussion in the third trimester of pregnancy.[21] Bloodspot screening is carried out for up to 9 conditions, with some parental choice over the testing and report options.[22] Parental proxy consent is formally recorded in the newborn records, and additional written communication is required when parents decline testing (including notification to the GP and Child Health Information Service). The Public Health England (PHE) letter template – intended for parents declining blood spot testing – says that, while "screening is not compulsory, […] it is strongly recommended because it could save your baby's life".[23] This is then re-inforced by the warning that, unless parents change their minds about NBS, "there is a risk that your

[20] R. Botkin, *Ethical Issues in Newborn Screening*, cit., 255.

[21] Public Health England (PHE) issues many publications about newborn screening, many of which are aimed at healthcare professionals, and some of which are highly technical: see https://bit.ly/2HyWAnV (last accessed August 14, 2020). Information specifically for parents can be found at https://bit.ly/3awILBo (last accessed August 14, 2020).

[22] F. Ulph, S. Wright, N. Dharni, et al., *Provision of Information about newborn screening antenatally: a sequential exploratory mixed-methods project,* in *Health Technol,* 21, 55, 2017, Assess 1. Parents can only choose to have screening for all 6 Inherited Metabolic Diseases or none at all (PHE n 21).

[23] Available at, https://www.gov.uk/government/publications/declined-newborn-blood-spot-screening-template-letters (last accessed August 14, 2020).

child may become seriously ill and suffer irreversible harm".[24] The reasonable inference is that responsible parents would and should consider testing. Evidence shows that fathers are not always involved in the consent process[25] and, as we have already remarked, we cannot rule out the possibility of family discord.[26] Some concern has been expressed about the routinisation of testing and the inadequate provision of information to parents.[27] This suggests that some dilution of consent may be occurring in practice, either because the signalling is cursory or because the parents do not have adequate information to make an informed choice. Some aspects of the process – for example, whether to be involved in future research – appear to require a positive opt-out by the parent, suggesting that differential standards and interests are in play.[28]

Given this background, we might wonder whether the English model is actually closer to the *opt-out* variant. Two recent studies of the English NBS programme[29] shed some light on the matter. In the first of their studies, Ulph et al. note that the timing of information provision is critical to its effectiveness – with informational exchange shortly after birth being generally ineffective and third trimester exchange being a key time for informational assimilation. This study suggests that NBS design should focus on the informational needs of parents rather than upon the process of obtaining and formalising consent. In their second, qualitative, study Ulph et al. sought the views of healthcare professionals and parents about NBS consent processes in England. There was common consensus that dilution of consent was occurring in practice (this being expressed as doubts about the voluntary and informed aspects of the process). There was also some evidence that parents valued disclosure of information more than choice – with parents being happy to have any tests "for the health of their baby".[30] However, future retention and research use generated specific concerns about trust and differential views about consent,[31] suggesting that unitary approaches to consent may not be what parents want in practice.

3.2.4. Taking stock: extending NBS

How might a proposed extension of NBS (to collect genetic information) sit with the contemporary models that we have identified? Three points seem to be noteworthy.

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[24] *Ibid*.

[25] F. Ulph, N. Dharni, R. Bennett, T. Lavender, *Consent for newborn screening: screening professionals' and parents' views*, in *Public Health,* 178, 2020, 151, 156.

[26] C.A. Genetti, T.S. Schwartz, J.O. Robinson, *Parental Interest in Genomic Sequencing of Newborns: Enrollment Experience from the BabySeq Project*, in *Genetics in Medicine,* 21, 3, 2019, 622–630, doi:10.1038/s41436-018-0105-6, 6.

[27] F. Ulph, S. Wright, N. Dharni, et al., *Provision of Information about newborn screening antenatally: a sequential exploratory mixed-methods project*, cit.; F. Ulph, N. Dharni, R. Bennett, T. Lavender, *Consent for newborn screening: screening professionals' and parents' views,* cit.

[28] See https://bit.ly/2HyWAnV.

[29] F. Ulph, S. Wright, N. Dharni, et al., *Provision of Information about newborn screening antenatally: a sequential exploratory mixed-methods project*, cit.; F. Ulph, N. Dharni, R. Bennett, T. Lavender, *Consent for newborn screening: screening professionals' and parents' views,* cit.

[30] F. Ulph, N. Dharni, R. Bennett, T. Lavender, *Consent for newborn screening: screening professionals' and parents' views*, 154.

[31] *Ibid*.

First, it might be thought that where NBS is mandatory, there will be little resistance. However, the proposed extension will need to be squared with whatever background justification for screening is operative in the community. Even where the screening community is guided by whether there is a net benefit, there might be reservations about extending NBS in the absence of clear benefit to the child.

Secondly, if the benefits of an extension to NBS are uncertain, this has implications not only for benefit-focused mandatory regimes but also for advocates of parental rights and consent.[32] As the benefits to the test subject dwindle and any correlative parental duty to screen is weakened, the ability to deliver workable informed consent processes becomes more problematic. The expression of gene variation is shaped by a range of internal/external factors that make whole exome or genome results difficult to interpret or to counsel upon either in advance or once results are available.[33] Moreover, although parents might be given more screening options to which they can say yes or no, the complexity of the choices presented may mean that, while parents are able to make more decisions, the decisions that they make are less meaningful.[34] In short, more choice coupled with more information does not necessarily translate into better choices.

Thirdly, creating what are in effect genetic profiles for the newborn, raises familiar broader concerns about the social impact of genetic information.[35] Whatever our ethics, these broader concerns apply. Capturing these concerns, a Hastings Center Report says that "mapping and classifying people's genomes would undermine their privacy; lead to new forms of discrimination (by employers and insurers, for example); foster the essentialist idea that people are their genes; bolster attempts to interpret social identities in biological terms; and trigger depression, anxiety, suicidality, and worry in individuals whose genetic risk for certain conditions was determined to be high. In addition, some cautioned that a genetics focus would lead to lessened emphasis on the social determinants of health and health disparities among underserved groups (such as racial or ethnic minorities)".[36]

In sum, we should not assume either that those who advocate the extension of NBS will be pushing at an open door in mandatory regimes, or that those who are trying to operationalise an opt-in model (along the lines of the ideal-type) will find it easy to do so. Possibly, the most likely defection from the ideal-typical model will be in those regimes that pay lip service to opt-in but which, in practice, are actually closer to opt-out. In this context of parents being already nudged towards consent, practice is likely to fall short of the aspirational relational process, and the information given to parents is likely to be unsatisfactory.

[32] See, e.g., .R. BOTKIN, *Ethical Issues in Newborn Screening,* cit., 260.

[33] J. JOHNSTON et al., *Sequencing Newborns: A Call for Nuanced Use of Genomic Technologies, The Ethics of Sequencing Newborns: Recommendations and Reflections, special report,* in *Hastings Center Report,* 48, S2, 2018, DOI: 10.1002/hast.874. See also K.H. ROTHENBERG, L.W. BUSH, *The Drama of DNA: Narrative Genomics*, Oxford, 2014.

[34] G. DWORKIN, *The Theory and Practice of Autonomy*, Cambridge, 1997; F. ULPH, S. WRIGHT, N. DHARNI, et al., *Provision of Information about newborn screening antenatally: a sequential exploratory mixed-methods project,* cit.

[35] See, e.g., Human Genetics Commission, *Profiling the Newborn: a Prospective Gene Technology*?, January 2005.

[36] J. JOHNSTON et al., *op.cit.,* S16.

3.3. The range of decisions to be made around NBS

For the screening community and policymakers, it is not just a matter of deciding whether or not to offer NBS; and, concomitantly, for parents it is not just a matter of saying yes or no to NBS. There are decisions to be made about which particular diseases and conditions to screen for, about the return of findings, and about the retention of data and samples.

First, a decision has to be made about whether to limit NBS to treatable/remediable conditions, or extend it to a range of late onset conditions or carrier conditions. In part, this may be influenced by the analytical validity,[37] clinical validity[38] and the clinical utility[39] of the screening test. The limitation of many NBS programmes to treatable conditions provides an obvious fulcrum for activism,[40] but keeps the focus firmly on the direct interests of the test subject and makes the benefit/harm assessment much easier.

Second, a decision has to be made about which findings are reported back by the laboratories and retained in the data records. Laboratories may control the reporting/recording process, although this will probably be determined or influenced by health policies or instructions from the healthcare professionals and/or parents. Decisions have to be made about whether to report back incidental findings – where information about a condition or risk is identified but was not the subject or original purpose of the test.[41] This gives rise to a vexed discussion about the existence of a right to know and right not to know, and to the respective rights' holder in this context.[42] Decisions have to be made about what happens to the retained and unfiltered findings.[43] There might be concerns about having any findings, uncertain or otherwise, permanently linked to a child's medical or other data records and what implications it might have for their future.[44] Further, there is a question about whose interests should feature and be prioritised at this stage of the process. Even if newborn interests have primacy at the "decision to test" stage, the interests of other family members might need to be brought into account once there are incidental findings that concern and potentially benefit them.[45] If reporting back to the family reduces the diagnostic odyssey, or enables parents to be forewarned

[37] The ability to detect the trait/condition it seeks (sensitivity and specificity).

[38] The predictive accuracy of the test.

[39] The ability and usefulness of any test to improve the health/wellbeing of the person tested.

[40] Compare, the Genetic Alliance UK, *Fixing the present, building for the future: Newborn screening for rare diseases*, 2019, 16, where it is claimed that the UK screens for relatively few diseases compared to other high-income countries.

[41] Generally, see S. VAN DER BURG, A. OERLEMANS, *Fostering caring relationships: Suggestions to rethink liberal perspectives on the ethics of newborn screening,* in *Bioethics,* 32, 2018, 171.

[42] For discussion: J. WALE, *Regulating disruptive technology and informational interests in the arena of reproductive tests,* in *Journal of Information Rights, Policy and Practice*, 3, 1, 2019, available at: https://jirpp.winchesteruniversitypress.org/articles/abstract/24/; R. BROWNSWORD, J. Wale, *The Right to Know and the Right Not to Know Revisited*, in *Asian Bioethics Review*, 2017, 1-16, doi:10.1007/s41649-017-0012-1; B DAVIES, *The right not to know and the obligation to know*, *Journal of Medical Ethics,* 2020, 1-4, doi:10.1136/medethics-2019-106009.

[43] B.A. TARINI, A.J. GOLDENBERG, *op.cit.*; Genetic Alliance UK, *Fixing the present, building for the future: Newborn screening for rare diseases*, cit., 18.

[44] C.A. GENETTI, T.S. SCHWARTZ, J.O. ROBINSON, et al., *op.cit.*

[45] J. JOHNSTON et al., *op.cit.*

of possible risks in future pregnancies,[46] those who espouse a utilitarian or communitarian ethic might be attracted by a broad obligation to return incidental findings.[47] However, for those who aspire to keep faith with the ideal-typical model of consent, there is no easy option: whether the parents are invited to make a blanket yes or no decision about the return of findings, or asked to make a more nuanced choice, this looks like a major challenge for informed consent.

Third, there are decisions to be made about what data and samples are retained, for how long and for what purposes. FIGO have suggested that later sample use – for retrospective testing or research purposes – requires written permission. This is a more parent-centric position when compared to their stance on testing,[48] and is supported by empirical evidence showing that many parents prefer to make informed choices in the context of blood spot storage and subsequent research use.[49] In terms of existing laboratory data – whether reported back or otherwise – there are issues of privacy, trust, and possible future prejudice or discrimination.[50] England uses a default blood spot retention period of "at least 5 years", with standard use covering quality improvement and "research to help improve the health of babies and their families in the UK".[51] The screening results are also recorded in various health information systems. Identity is supposed to be anonymised if the samples are used for research purposes, and the parents have to formally opt out of research if they have agreed to screening. This highlights some ambivalence in screening policy and practice: namely, is screening for the benefit of the test subject, or is it to collect/retain samples for research purposes and for wider societal benefit?[52] Some might argue that if we can achieve both aims, there will be no wrong done to the test subject. However, this win-win argument implies a utilitarian approach that either displaces rights and consent or downgrades parental rights.

Pulling together the strands of this discussion, if NBS is extended in order to capture more genetic information, the potential complexity of decision-making will challenge the commitment to both the sovereignty and the validity of consent.[53] Where consent is formalised before testing in a single

[46] .R. BOTKIN, *Ethical Issues in Newborn Screening*, cit.

[47] See for eg., M.S. GROSS, A.R. RUTH, S.A. RASMUSSEN, *Respect women, promote health and reduce stigma: ethical arguments for universal hepatitis C screening in pregnancy*, *Journal of Medical Ethics,* 2020, 1-4 DOI:10.1136/medethics-2019-105692.

[48] Figo Committee Report, *Ethical aspects concerning neonatal screening FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health,* cit.

[49] F. ULPH, S. WRIGHT, N. DHARNI, et al., *Provision of Information about newborn screening antenatally: a sequential exploratory mixed-methods project,* cit.

[50] See for e.g., C.A. GENETTI, T.S. SCHWARTZ, J.O. ROBINSON, et al., *op.cit.*

[51] See https://bit.ly/2HyWAnV. Interestingly, the destruction of residual blood spot cards is currently embargoed while the associated Code of Practice is being reviewed (available at: https://www.nhs.uk/conditions/pregnancy-and-baby/newborn-blood-spot-test/).

[52] E.W. ROTHWELL, R.A. ANDERSON, M.J. BURBANK et al., *Concerns of Newborn Blood Screening Advisory Committee Members Regarding Storage and Use of Residual Newborn Screening Blood Spots*, in *American Public Health Association*, 2011, DOI 10.2105/AJPH.2010.200485.

[53] For example, see WHO, *Medical Genetic Services in Developing Countries: The Ethical, Legal and Social Implications of Genetic Testing and Screening,* 58, 2006, para 4.6.2, for the view that valid informed consent (in the context of genetic testing) "requires a bilateral process involving a dialogue of questions and answers between the individual considering testing and the person obtaining informed consent (often a health care professional). This dialogue requires the person obtaining informed consent to gauge the appropriate level of language and technical detail suitable for the individual's understanding".

(agreement) transaction, with informational exchange occurring shortly before and after birth, there are already concerns about informed consent; and so, we can have no confidence that these processes will improve in the event of expansion. While those with a reformist agenda have suggested that we may do better to focus on the informational needs of parents rather than the moment of consent itself,[54] others have mooted differential consent arrangements where the direct benefit test cannot be met.[55] A further option might be to break down decision-making and consent processes into more manageable elements. While there could be resource and uptake issues if parents were approached about retention/research options at a later date, the advantage may be that critical decision-making will be occurring in less hectic and more informed contexts. Alternatively, stratified informed consent processes could be used where the informational exchange is dependent on what parents want to know.[56]

While there is much to be said about these ideas, which clearly merit further consideration, we cannot explore them any further here. For present purposes, suffice it to say that the practical challenge of keeping faith with parental rights and the sovereignty of consent should not be under-estimated.

3.4. Legitimate interests and the scope of parental rights

It is one thing to argue that parents have a legitimate interest in making their own choices; but it does not follow that parents should be able to choose just what they want.[57] In a community that takes rights and consent seriously, there will be decisions to be made about the limits to, and scope of, parental rights and about the resolution of competing and conflicting rights.

3.4.1. Limiting parent autonomy

Most communities accept that parental autonomy is not absolute,[58] that some limits have to be be placed on parental freedom vis a vis their children.[59] Criminal frameworks typically regulate both positive conduct and omissions that harm or have the risk of seriously harming children. Regulation

[54] F. Ulph, N. Dharni, R. Bennett, T. Lavender, *Consent for newborn screening: screening professionals' and parents' views* , cit.; S. Van der Burg, A. Oerlemans, *Fostering caring relationships: Suggestions to rethink liberal perspectives on the ethics of newborn screening,* cit.

[55] B.A. Tarini, A.J. Goldenberg, *op.cit.*; but, concern has been expressed about the practical implications of these approaches, see J.R. Botkin, *Waving Goodbye to Waivers of Consent*, in *The Hastings Center Report*, 45, 6, 2015, DOI: https://doi.org/10.1002/hast.520.

[56] E.M. Bunnik, A. de Jong, N. Nijsingh, *The new genetics and informed consent: Differentiating choice to preserve autonomy*, in *Bioethics,* 27, 2013, 348-355.

[57] For discussion in the context of non-invasive pre-natal testing, see R. Brownsword, J. Wale, *Testing Times Ahead: Non-Invasive Prenatal Testing and the Kind of Community that We Want to Be*, in *Modern Law Review,* 81, 2018, 646.

[58] A. Newson, *Should Parental Refusals of Newborn Screening Be Respected?*, in *Cambridge Quarterly of Healthcare Ethics,* 15, 2, 2006, 135-146.

[59] In the UK, these limits may be influenced by the age, maturity, and capacity of the child (*Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112; *Re D (A Child)* [2019] UKSC 42). At international level, there is legal recognition that interventions against individuals without capacity to consent must generally be undertaken for their direct benefit: *Oviedo Convention on Human Rights and Biomedicine*, Council of Europe Treaty no 164, Art 6(1).

and prohibition can be general, applying to all human persons,[60] and addressing specific categories of person (eg minors)[61] or relationships.[62] Commonly there will be legal frameworks regulating the acquisition of legal responsibility and authority for a minor;[63] and, wardship and care proceedings can restrict or qualify the rights and responsibilities of natural parents over their children.

What is more controversial is the nature and extent of the obligations that parents owe to their children in terms of general nurture, environment, and life choices. There has been much discussion around whether children have a right to an open future,[64] and what, if any, correlative parental obligations there might be: for example, are there parental duties to preserve or not close down future options for children?[65] In the seminal case of *Gillick*, Lord Scarman claimed that the purpose of parental power and control over the person and property of a child: "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".[66]

Thus envisaged, a parent can consent or withhold agreement to NBS in discharge of their duty to maintain or protect, with moral limits or boundaries that are capable of extending beyond any legal constraint or interference by the State. This is important because NBS is capable of yielding information that could compromise or impede the future life options of the test subject – for example, a genetic disorder that may never become symptomatic which is nonetheless a condition to be disclosed for insurance or employment purposes later in life. Framing parental consent as necessary to the extent that it serves the interests of the newborn, offers a platform to circumvent or qualify the sovereignty of consent. However, if the question is about the interests of a baby, rather than about proxy consent as such, a new point of dispute is introduced into the relationship between parents and healthcare professionals.

3.4.2. Competing and conflicting interests

Where parental interests are set against societal interests, the issue is often framed in terms of private against public interest, with the former operating as an "effective discussion stopper"[67] against those advancing wider societal claims. However, the relationship between the public and private is unstable and there are overlaps between these domains that make this division potentially problematic. The issue is therefore not simple recognition of the existence of a private or public interest in screening newborns, rather it is determining which interests – particularly interests in autonomy and in informed consent – are legitimate in the circumstances, and where the balance of interests and resulting priorities rest.

[60] For our purposes, born humans beings that qualify for legal protection. We accept that there might be qualified protection for those beings in persistent vegetative/ brain dead states (*Bland v Airedale NHS Trust* [1993] AC 789).

[61] Sexual Offences Act 2003.

[62] *Ibid*, S16.

[63] Children Act 1989 (as amended).

[64] J. FEINBERG, *The Child's Right to an Open Future*, in *Freedom and Fulfillment*, Princeton, 1992.

[65] J. WALE, *Regulating disruptive technology and informational interests in the arena of reproductive tests,* cit.

[66] *Gillick v West Norfolk and Wisbech Area Health Authority*, cit., para 185E.

[67] S. VAN DER BURG, A. OERLEMANS, *Fostering caring relationships: Suggestions to rethink liberal perspectives on the ethics of newborn screening*, cit., 181.

To start with the interest in autonomy, even if it is agreed that parents have an interest in making *their own* choices, or in a "sphere of decision privacy",[68] this leaves open to debate the range of choices or decisions that should be available to parents. Moreover, because newborn infants do not have the immediate capacity to make their own choices, this gives the State a potential foothold in decision-making – for example, it might be argued that concerns about vaccination, education or other significant health risks that might cause serious harm to a child, justify the use of the *Parens Patriae* jurisdiction to override any parental refusal or action.[69] That is not to say that the Courts will necessarily discount parental views, but it does mean that it is far easier for State actors to claim a legitimate interest in decisions that concern those without capacity to act and make choices independently.

Nevertheless, is it legitimate for the State to compel acts that are designed to protect or prevent possible serious harm to a child, even if that child is asymptomatic? A claim might be made that NBS serves a moral imperative or moral responsibility to ensure the health of natural children[70] – but this is surely doubtful when using whole exome or genome sequencing. Short of compulsion, the State may influence practices by encouragement, nudges and incentives around NBS.[71] That said, at all levels, State actors need to be mindful that NBS programmes need parental support and endorsement to be effective, and policymakers alienate parents at their risk. Accordingly, healthcare professionals have to balance the need for parental trust, harm avoidance and the delivery of beneficent outcomes for test subjects.[72]

Against the idea of a parental *right* to autonomy, the emphasis is sometimes on "duty". Indeed, in the seminal case of *Montgomery v Lanarkshire Health Board,*[73] the primary concern of the court in the negligence action was whether the treating doctor had complied with the duty owed to the pregnant patient in terms of informational exchange. These references to the duties of doctors could be simply the other side of patients' rights; but, they might also betray an adjustment to the scope or weight of the interest and, in effect, a downgrading of the right.[74]

Turning to the parents' interest in being informed, it was recognised in *Montgomery* that "the doctor's duty is not fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent

[68] Compare J. WILSON, *Is respect for autonomy defensible?*, in *Journal of Medical Ethics,* 33, 2007, 353.

[69] See for example, *Re C (A child) (HIV testing)* [2000] 1 WLR 2. *Parens Patriae* is the authority of the State to protect those that are unable to protect themselves. International legal instruments (eg. the *Oviedo Convention*, Art 6(1)) might prefer to frame the intervention in terms of potential benefit rather than harm.

[70] See for eg., F. ULPH, N. DHARNI, R. BENNETT, T. LAVENDER, *Consent for newborn screening: screening professionals' and parents' views*, cit., 155.

[71] A. NEWSON, *Should Parental Refusals of Newborn Screening Be Respected?,* cit.

[72] S. VAN DER BURG, A. OERLEMANS, *Fostering caring relationships: Suggestions to rethink liberal perspectives on the ethics of newborn screening*, cit., 180.

[73] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

[74] See, further, B.J. RICHARDS, *Autonomy and the Law: Widely Used, Poorly Defined,* in D.G. KIRCHHOFFER, B.J. RICHARDS (eds), *Beyond Autonomy: Limits and Alternatives to Informed Consent in Research Ethics and Law*, Cambridge, 2019; and, M. DUNN, K.W.M. FULFORD, J. HERRING et al., *Between the Reasonable and the Particular: Deflating Autonomy in the Legal Regulation of Informed Consent to Medical Treatment,* in *Health Care Analysis,* 27, 2018, 110.

form".[75] Informational transfer on its own is insufficient and there needs to be some level of patient understanding and knowledge about the available choices, risks etc.[76] Whether viewed as a right or as a duty, the challenges associated with securing participant understanding are amplified where genomics are involved.[77] Exactly how far healthcare professionals need to go to unearth understanding and values before seeking consent and undertaking invasive investigation or treatment remains unclear. What is reasonably clear is that informed consent processes may have a value if they facilitate and evidence the knowledge and understanding of those who provide consent. Mere written agreement or verbal affirmation to the investigation or interference is unlikely to meet these objectives.

While some might jib at the sovereignty of consent, thinking that it overplays the legitimate interests of parents, there is more likely to be assent to the sufficiency of consent and to there being at least a prima facie case for parents playing a central role in NBS decision-making. There are also good and independent reasons why many screeners, even if they are not dyed-in-the-wool rights theorists, might want to insist on a demanding threshold for a valid consent – by seeking a free and informed consent, healthcare professionals signal respect, maintain trust and help avoid legal disputes.[78] Certainly, where a community takes rights seriously, the burden should be on those who want to either de-centre or dilute consent to justify such modification or relaxation.

3.4.3. Taking stock

From the many particular points made in the course of our discussion, there are perhaps four key points to highlight. First, even in ordinary times, biolegal and bioethical debates do not stand still. We now live in an age of genomics (and other omics) all creating new opportunities but also challenges for the governance of NBS. Screening today is not screening as Wilson and Jungner knew it. Secondly, for at least two reasons, mapping and classifying NBS regimes relative to our ideal-typical model of consent is not straightforward. One reason is that there can be some distance between the promise of screening regimes and their actual practice. Another reason is that NBS programmes involve a number of elements each of which, in principle, could be subject to parental consent. So, mandatory regimes that do not require parental consent in relation to the basic elements of NBS and the storing of blood might make consent a requirement in relation to other elements (such as the return of findings). Thirdly, the complexity of genetic data means that, even if the sovereignty of consent is not questioned, even if there is no resistance to parental rights – admittedly, an unlikely scenario in biolaw and bioethics as we have come to know them in ordinary times – the implementation of the ideal-typical model of consent will be a major challenge. Fourthly, while we can identify the four critical points at which pressure might be applied to a rights-based regime and parental consent, we cannot always anticipate from which ethical constituency pressure will be applied any more than we

[75] *Montgomery v Lanarkshire Health Board*, at para 90 (Lords Kerr and Reed).
[76] B.J. RICHARDS, *Autonomy and the Law: Widely Used, Poorly Defined*, cit., 30.
[77] N. ASHLEY, M.A. TOMLINSON, D. SKINNER et al., *"Not tied up neatly with a bow": Professionals' Challenging Cases in Informed Consent for Genomic Sequencing*, in *Journal of Genetic Counseling*, 25, 1, 2016, 62-72, doi:10.1007/s10897-015-9842-8.
[78] F. ULPH, S. WRIGHT, N. DHARNI, et al., *Provision of Information about newborn screening antenatally: a sequential exploratory mixed-methods project,* cit.

can anticipate where pressure will be applied or the form that it will take – whether it is to displace or downgrade rights or to de-centre or dilute consent. Furthermore, predicting the outcomes of debates and disputes around the proposed expansion of NBS is not easy. In the cut and thrust of these debates, our ideal-typical model of consent and the rights on which it is based might or might not hold their ground.

4. In Extraordinary Times: Proxy Consent and Pandemics

From ordinary times, we turn to extraordinary times. In ordinary times, the pattern of debate in biolaw and bioethics, although pluralistic and contested, is reasonably familiar; the conversation is one we know. In extraordinary times, there is a different conversation, one that might employ familiar ideas but one that appeals to justifications that are far from ordinary.

If recent experience with CoViD-19 is representative of the way in which communities (local, regional, and international) reason during the time of a pandemic, then it is pretty clear that the case for public health measures does not rest on the consent of individuals. It is pretty clear, in other words, that if parents were to try to stand on their rights and resist, say, the vaccination of their children or some other harm-reducing measure advised by public health professionals, there would be a major push-back[79]. Similarly, we would expect there to be a push-back if parents were to resist or refuse to consent to the participation of their babies or children in non-invasive studies that epidemiologists believe would illuminate our understanding of the nature of the pandemic-causing virus. In this part of the article we sketch the changing rhetoric; we relate this to three possible accounts that purport to explain and to justify the displacement of rights and consent; and then we suggest that one of these accounts, engaging the idea of a stewardship responsibility for the global commons,[80] offers the best account of what makes any particular time or issue "extraordinary" and, with that, offers the best understanding of the extent to which rights and consent are justifiably displaced.

4.1. Rights and Consent Superseded

In extraordinary times, even in a community of rights, consent is not everything. Alongside ordinary times conversations and contestation, there are new priorities and a sense that we are now operating beyond both biolaw and bioethics as we ordinarily know them.

[79] That said, to a certain extent, this is context-sensitive. For example, a recent poll in the USA, suggests that about a third of US adults would decline a vaccine for CoViD-19 and, presumably, these adults would also push-back against mandatory vaccination of their children: see S.M. O'KEEFE, *One in Three Americans Would Not Get COVID-19 Vaccine*, August 7, 2020, available at https://news.gallup.com/poll/317018/one-three-americans-not-covid-vaccine.aspx (last accessed August 28, 2020).

[80] Compare, Nuffield Council on Bioethics, *Public health: ethical issues*, November 2007. The Council's reliance on the concept of stewardship attracted some criticism as being (from a utilitarian perspective) unnecessary. However, provided that stewardship is understood as operating in a different (extraordinary times) domain from ordinary time utilitarian reasoning, it is an evocative and defensible idea. For defence, see T. BALDWIN, R. BROWNSWORD, H. SCHMIDT, *Stewardship, Paternalism and Public Health: Further Thoughts,* in *Public Health Ethics,* 1, 2009, and R. BROWNSWORD, *Regulation: Prudence, Precaution and Stewardship*, in *Northern Ireland Legal Quarterly,* 62, 2011, 573.

If this meant that, in extraordinary times, there are no longer legal or ethical constraints or that we should submit to a Leviathan, this would be deeply worrying. However, this is not the case: there remains a conspicuous concern to do the right thing. For example, the European Group on Ethics in Science and New Technologies (EGE) concludes its *Statement on European Solidarity and the Protection of Fundamental Rights in the COVID-19 Pandemic* with the following ringing declaration: "[w]e must live through this pandemic, and after it. We must face this situation with strength, care and solidarity – a social vaccine that accompanies our search for a CoViD-19 vaccine, which has an enduring character. One that provides resilience, lasting social and economic solidarity and *lasting immunity against indifference*".[81]

Nor is it the case that rights-based thinking is displaced from conversations that bring ordinary times values to bear on governance in extraordinary times. Indeed, the EGE, echoing the concerns of civil libertarians, insists that the unprecedented quarantine measures that were adopted to confine the spread of the virus, the extended use of surveillance technologies, and the like, should respect human rights by being no more than necessary and proportionate. As the EGE says, "[t]he public health emergency must not be abused to usurp power, or to permanently suspend the protection of rights and liberties".[82] This is also not to say that concerns about consent are altogether set aside – for example, if children or their parents were to be conscripted into research trials, or if post-mortem samples were to be taken by researchers without consultation with families, it would be no surprise at all if consent were to re-surface as a basic requirement.[83] Nevertheless, the dominant thoughts provoked by a pandemic are about taking measures that, all things considered, will be for the benefit of human health and well-being, about keeping people safe, about reducing avoidable pressure on the healthcare infrastructure, and about maintaining social solidarity.

This shift in thinking prompted by pandemics implies that, in some circumstances, where communities are faced by emergencies or catastrophes, neither the consent of individuals nor their particular rights are central to our justificatory thinking.[84] Instead, there is a renewed emphasis on collective well-being and responsibility. Reflecting this shift, in its *Statement on COVID-19: Ethical Considerations from a Global Perspective*, the UNESCO International Bioethics Committee says that the responsibilities include those of "governments to ensure public safety and protect health, and raise awareness of the public and other actors on the methods required for this purpose; responsibilities of the public to abide by the rules that protect everyone not only as individuals but also, and above all, as a community; [and] responsibilities of healthcare workers to treat and care for patients".[85]

[81] Statement issued April 2, 2020, p 4, emphasis supplied. Available at https://bit.ly/3apLyMM (last accessed July 7, 2020).

[82] Recommendation 4. Compare M.M. MELLO, C.J. WANG, *Ethics and governance for digital disease surveillance*, in *Science,* 368, 6494, 2020, 951.

[83] Compare K. MOODLEY, B.W. ALLWOOD, T.M. ROSSOUW, *Consent for critical care research after death from COVID-19: Arguments for a waiver*, *South African Medical Journal,* 2020, 629-634.

[84] That said, the idea of collective consent (which, of course, departs from our ideal-type) might play a role in weakening the significance of individual rights and personal consent.

[85] SHS/IBC-COMEST/COVID-19, Paris, 26 March 2020.

The question then is this: in which circumstances are there compelling reasons for refocusing our justificatory reason in this way? How should we account for the displacement of rights and consent?

4.2. Three Accounts of the Displacement of Rights and Consent

We suggest that there are three principal narratives that might both explain and defend the displacement, in exceptional times, of rights and consent. Here, we will simply sketch the three accounts and then we will elaborate on the third narrative in the next sub-section of the article.

The first narrative is along the lines that the scale and immediacy of the threat represented by a pandemic takes us into a "state of exception". In these exceptional circumstances, ordinary bioethics is suspended. The imperative is to respond to the threat in a way that will prevent the spread of the infection and mitigate its harmful effects. Basically, governments and public health agencies must do whatever it takes. As we have already said, the rhetoric around CoViD-19 does not entirely fit with this narrative and, more importantly, to give "the authorities" a licence of this kind is a hostage to fortune – if "states of exception" are to be recognised, they need to be for no longer than absolutely necessary.

The second narrative treats a pandemic as a radical change to the context in which bioethics is ordinarily conducted but it resists the idea that bioethics is now suspended and superseded by a state of exception. To the contrary, bioethics as practised in ordinary times now extends into extraordinary times, but the pattern of advantage and disadvantage alters because of the radical change in context. Whereas, in ordinary times and ordinary contexts, the ethic of rights and consent is an important voice in bioethical debate, in extraordinary times and extraordinary contexts, this voice loses its power and influence. In other words, our attraction and commitment to an ethic of rights and consent is context-dependent; and, in some exceptional circumstances, that attraction and commitment weakens.

The third narrative rejects the idea that a pandemic introduces a state of exception in the sense of a licence for governments to do whatever it takes; and it also rejects the idea that the pandemic simply changes the context in which ordinary times bioethical contestation takes place. Rather, the third narrative identifies the pandemic as a particular threat to the conditions which make it possible to adopt bioethical positions and to engage in bioethical arguments in the first place. In the third account, we are reminded not only of the vulnerability of humans and the fragility of the global commons on which all forms of human social existence depend, but also that, while some threats to the commons are *acute* (as is the case with a pandemic), others are *chronic* and *incremental* (as is the case, for example, with climate change and with big data and surveillance). By contrast with the first two accounts, in which there is a period of ordinary times, then a period of extraordinary times before a return to ordinary times, the third account holds that, even in what are ostensibly ordinary times with their standard debates, there needs to be the kind of monitoring, vigilance, and precautionary preparedness that is appropriate in extraordinary times.

Following this third account, ordinary time conversations and ordinary case justifications co-exist with what we are calling extraordinary time conversations and stewardship justifications. In this bigger picture, where stewardship justifications are brought into play (whether by acute or by chronic threats) it is not a case of the triumph of one kind of ordinary case justification, it is not the

values of one community (where neither rights nor consent are taken seriously) displacing the values of another community (where rights and consent are taken seriously), but a case of stewardship responsibilities for the global commons supervening on the values of all communities.

4.3. Stewardship and the Global Commons

The global commons has two dimensions: one relates to human existence; and the other relates to the human capacity for agency. In the case of a pandemic such as CoViD-19, there is an urgent need not only to protect the conditions for human life but also to minimise the compromising of the context for agency.

First, the *human* species is defined by its biology; and the prospects for human life depend on whether the conditions are compatible with the biological characteristics and needs of the *human* species. Most planets will not support *human* life. The conditions on planet Earth, neither too hot nor too cold, are special for *humans*. However, the conditions are not specially tailored to the needs of any particular human; these are the generic conditions for the existence of any member of the human species.

Secondly, it is characteristic of human *agents* that they have the capacity to choose and to pursue various projects and plans whether as individuals, in partnerships, in groups, or in whole communities. Sometimes, the various projects and plans that they pursue will be harmonious; but, often, human agents will find themselves in conflict or competition with one another. However, before we get to conflict or competition, there needs to be a context in which the exercise of agency is possible. This context is not one that privileges a particular articulation of agency; it is prior to, and entirely neutral between, the particular plans and projects that agents individually favour; the conditions that make up this context are generic to agency itself.

Any human agent, reflecting on the antecedent and essential nature of the commons must regard the critical infrastructural conditions as special. From any practical viewpoint, prudential or moral, that of regulator or regulatee, the protection of the commons must be the highest priority.[86] Protective stewardship will be guided by three imperatives.

In the first instance, it is imperative that steps are taken to protect, preserve and promote the natural ecosystem for human life.[87] At minimum, this entails that the physical well-being of humans must be secured; humans need oxygen, they need food and water, they need shelter, they need protection against contagious diseases, if they are sick they need whatever medical treatment is available, and they need to be protected against assaults by other humans or non-human beings.

The second imperative is to construct and maintain the conditions for meaningful self-development and agency: there needs to be a sufficient sense of self and of self-esteem, as well as sufficient trust

[86] An understanding of what it is to have the capacity for agency presupposes respect for the conditions for both self-interested agency and other-regarding agency. To cash out this argument, see A. GEWIRTH, *Reason and Morality*, Chicago, 1978; D. BEYLEVELD, *The Dialectical Necessity of Morality,* Chicago, 1991; and ID., *What Is Gewirth and What Is Beyleveld: A Retrospect with Comments on the Contributions*, in P. CAPPS, S.D. PATTINSON (eds), *Ethical Rationalism and the Law,* Oxford, 2017, 233.

[87] Compare, J. ROCKSTRÖM et al., *Planetary Boundaries: Exploring the Safe Operating Space for Humanity*, in *Ecology and Society*, 14, 2009, 32, available at: http://www.ecologyandsociety.org/vol14/iss2/art32/ (last accessed November 14, 2016); and, K. RAWORTH, *Doughnut Economics*, London, 2017, 43-53.

and confidence in one's fellow agents, together with sufficient predictability to plan, so as to operate in a way that is interactive and purposeful rather than merely defensive. The context should support agents in being able to freely choose their own ends, goals, purposes and so on ("to do their own thing") as well as to form a sense of their own interests and identity ("being their own person").[88] With existence secured, and under the right conditions, human life becomes an opportunity for agents to be who they want to be, to have the projects that they want to have, to form the relationships that they want, to pursue the interests that they choose to have and so on.

Thirdly, the commons must secure the conditions for an aspirant moral community, whether the particular community is guided by teleological or deontological standards, by rights or by duties, by communitarian or liberal or libertarian values, by virtue ethics, and so on. The generic context for moral community is impartial between competing moral visions, values, and ideals; but it must be conducive to "moral" development and "moral" agency in a formal sense. In particular, moral community of any kind presupposes a context in which agents are free to form and then to act on their own judgments of what it is to do the right thing.[89]

While respect for the commons' conditions is binding on all human agents, it should be emphasised that this does not rule out the possibility of prudential or moral pluralism. Rather, the commons represents the pre-conditions for both individual self-development and community debate, giving agents and communities the opportunity to develop their own view of what is prudent as well as what should be morally prohibited, permitted, or required. Whether the issue is the extension of NBS, or responding to a pandemic, or any other matter, it is the commons that provides the platform for such reflection, development, and debate.

5. Conclusion

This article has highlighted the challenges facing parents who, acting as proxies for their children, seek to stand on their rights and the need for their consent. Disputes around NBS are a case in point. Even in what we are calling ordinary times, the rights of parents and their giving or withholding of consent can come under increased pressure as developments in genetics offer reasons for undertaking more extensive screening. While such pressure might not displace rights, the conditions for a valid consent might be diluted. In what we are calling extraordinary times, the arguments against proxy consent become overwhelming: neither individual rights nor informed consent are now focal. Rather, it is our responsibilities as stewards of the commons that becomes the key justificatory consideration.

[88] Compare the insightful analysis of the importance of such conditions in M. BRINCKER, *Privacy in Public and the Contextual Conditions of Agency,* in T. TIMAN, B.C. NEWELL, B.-J. KOOPS (eds), *Privacy in Public Space*, Cheltenham, 2017, 64; and, similarly, see M. HU, *Orwell's 1984 and a Fourth Amendment Cybersurveillance Nonintrusion Test, Washington Law Review,* 92, 2017, 1819, at 1903-1904.

[89] See, e.g., R. BROWNSWORD, *Code, Control, and Choice: Why East is East and West is West,* in *Legal Studies,* 25, 2005, 1; ID., *So What Does the World Need Now? Reflections on Regulating Technologies,* in R. BROWNSWORD, K. YEUNG (eds), *Regulating Technologies,* Oxford, 2008, 23; ID., *Lost in Translation: Legality, Regulatory Margins, and Technological Management,* in *Berkeley Technology Law Journal,* 26, 2011, 1321.

The juxtaposition of ordinary time justifications with extraordinary time justifications opens an agenda for further inquiry. In particular, further reflection is invited on when the extraordinary is engaged and when it is not; on the character of extraordinary time reason, and any "reach-through" from one class of justifications to the other; and, on how to operationalise stewardship in extraordinary times.

With regard to the first question, we want to have the right justificatory conversation at the right time. To do this, we need to be clear about whether a particular question is appropriately treated as an ordinary times matter or whether it engages extraordinary considerations. For example, we have treated debates about the extension of NBS as an ordinary time matter – and we have no reason to think otherwise. However, in the context of a pandemic, some aspects of NBS might assume significance relative to mitigating the risks presented by the virus in which case this becomes a matter for extraordinary time justifications. Without such clarity, we might continue to rely on ordinary time justifications when the commons is already being compromised (as, for example, some might argue is the case with climate change); and, conversely, we might continue to rely on extraordinary time justifications when ordinary time considerations should be applied (as is the fear of civil libertarians about the persistence of restrictions imposed at the height of, and in the wake of, CoViD-19). In this light, we should be careful with narratives that imply that we live through a linear sequence of periods (ordinary, then extraordinary, then back to ordinary); rather, as the third narrative implies, we now live through a period in which the questions that we debate and the challenges that we face sometimes engage, as it were, ordinary time considerations but sometimes (as with climate change and pandemics) extraordinary time considerations.

Secondly, there are questions about the character of supervening reason and whether there is any reach-through of ordinary time values and justifications to extraordinary times. In ordinary times, we differentiate between prudential reason and moral reason. However, commons' protecting reason seems to be both prudential and moral; it is in the interest of everyone and it is categorical, exclusionary, and overriding. Beyond this particular question of character, as we have said, even in extraordinary times, some familiar ordinary times values will resurface in some debates (debates that actually belong to ordinary times). However, the question is whether values of this kind reach through to the stewardship of the commons. For example, some might argue that values such as autonomy, privacy, and human dignity are fundamental not only to the constitution of a community of rights but also to the context for agency that is one of the dimensions of the commons' conditions.

A third question, vividly highlighted by the recent experience with CoViD-19, is about the coordination of our stewardship responsibilities. In principle, we are all stewards for the global commons and, as such, we can "do our bit" – for example, we can comply with the necessary restrictions on our movement or association that are put in place to prevent the spread of the virus. However, in practice, the restoration and maintenance of the global commons needs international leadership.[90] In the case of a pandemic, it is the WHO that is the obvious candidate. However, if the

[90] See R. BROWNSWORD, *Redesigning the Institutional Framework II: International Institutions*, in ID., *Law 3.0: Rules, Regulation and Technology*, Abingdon, 2020.

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WHO is to be hobbled and undermined by great powers that conduct international relations in an entirely self-serving nationalistic way, there has to be some other approach.[91]

Finally, we might also reflect on the more general jurisprudential implications of the co-existence of ordinary time and extraordinary time justifications. While we might be more familiar with the former, it is in the latter that we have real terra firma for our justificatory arguments in biolaw and bioethics. If, as Sarah Franklin has argued, biolaw and bioethics have lost their bearings, then it is with our responsibilities in relation to the global commons that we should begin the work of restoration.[92] After all, unlike ordinary time debates where people find it hard to agree, no one should find it hard to agree that we should take special care of conditions that are neutral between humans, neutral between articulations of self-interest, and neutral between articulations of a moral viewpoint but without which humans cannot exist, cannot form a sense of their self-interest, and cannot exercise moral agency.

[91] See A. JOSEPH, H. BRANSWELL, *Trump: US will terminate relationship with the World Health Organization in wake of Covid-19 pandemic*, in *STAT*, May 29, 2020, available at https://bit.ly/3tGkW1B (last accessed, July 5, 2020).

[92] S. FRANKLIN, *Ethical research – the long and bumpy road from shirked to shared.* in *Nature,* 574, 2019, 627-630, doi: 10.1038/d41586-019-03270-4.