

# *Scientific Citizenship's Youngest Domain: Function Creep in Norway's Newborn Screening Programme*

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*Newborn screening (NBS) for inborn errors of metabolism and other serious conditions with onset during infancy is a widespread public health initiative. Like other screening programmes, it aims to discover and treat a disease before effects manifest themselves. Recently, there have been two prominent changes in NBS: a substantial increase in the number of conditions screened for and growing attention to secondary use of residual newborn blood spots. Here, we analyse how this latter change has transpired in Norway.*

*In 2018, Norway's parliament sanctioned the secondary use of NBS samples for epidemiological research unrelated to NBS. This broadened the programme's scope, co-opting it for research purposes, making samples available for inclusion in Norway's biobanking strategy. We argue that this transformation is a case of function creep, whereby the function of screening samples is expanded to serve purposes other than helping newborns. The process provided only minimal involvement from ordinary citizens, but it transformed screened infants into potential scientific citizens. Henceforth, all future generations of Norwegians must choose to stay in or opt out of biobank research when they turn sixteen. Additionally, consenting to this research may occasion a second form of function creep, as 'actionable findings' are fed back to participants.*

**Keywords:** Newborn screening, biobanking, scientific citizenship, function creep, secondary use of blood spots

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## Introduction

BIOMEDICAL ACTIVITIES have become more complex in recent decades, as illustrated by the hybridisation of clinical medicine and medical research (Hallowell, 2018), and of clinical and preventive medicine (Skolbekken, 2008). Here, we analyse yet another hybridisation in biomedicine—that of medical screening and medical research—focussing on how this development may affect the citizenship status of future generations.

Most screening programmes are named after the condition screened for or the technology applied in the screening, for example, breast cancer screening and colonoscopy screening. Newborn screening (NBS), meanwhile, foregrounds the target population and the timing of the testing. Timing is critical in this screening, which takes place in the first few days of life, as conditions typically included in NBS panels have in common that early death or permanent disability can be averted when affected infants are detected before symptoms appear, or that early treatment may improve the typical course of a severely debilitating condition. Early detection and early intervention are meant to alleviate suffering in the individual, as well as reduce the burden of disease on the individual, the family and the community (Kelly et al., 2016). Once simply known as the PKU test (for phenylketonuria, the first condition for which newborns were routinely screened), the flexibility inherent in the name has proved practical; the most wide-ranging programmes screen for over 50 conditions and the numbers are still rising (Health Resources & Services Administration, 2019; Timmermans & Buchbinder, 2013).

NBS is provided on all continents, though the number and composition of tests on the screening panel differ, and there are still areas of the world with rudimentary or non-existent screening programmes (Therrell et al., 2015). Many factors affect the composition and scope of a screening programme, including the prevalence of specific conditions in various populations and the availability of infrastructure, technology, funding, and treatment. Despite global variations, there have been two universal, prominent changes in NBS over the last decades: a substantial increase in the number of conditions for which screening is possible and a growing attention to secondary use of residual newborn blood spots. Such use has become possible largely by virtue of developments in genomics, making the blood spots a source of genetic knowledge and making NBS part of a gene world (Timmermans & Shostak, 2016). We analyse how these changes have unfolded in Norway and identify implications for future generations' citizenship status.

### **Norway: A Small Country with an Ambitious Biobanking Strategy**

Norway has a small population of 5.3 million (SSB, 2019), but a strong ambition of capitalising on the data its inhabitants generate through a rare combination of biobanks, health registries and patient records. Fundamental to the exploitation of these resources is the 11-digit national personal identity number. This represents the holy grail of epidemiology, allowing researchers to follow individuals

across rich data sets, like Norway's nineteen central health registries (see Frank, 2003). Norway looks to biobanking not only for its promise of improved public health, but also as an industry with the potential to secure public prosperity when the country's wealth from oil and gas is exhausted. Central to this is the belief that Norway possesses 'population cohorts, biobanks and health registries [that] are extraordinary resources for health research' (Stoltenberg et al., 2012, p. 135). Historically, Norwegian biobanking is rooted in research initiatives from the 1970s and the 1980s (Næss et al., 2007). This period saw a rapid increase in local health surveys and the emergence of the Cohort of Norway (CONOR), based on a small selection of health measures and survey questions included in all the collaborating surveys. In addition to these, blood samples were donated by CONOR participants. These samples would become part of another national strategy, the Biobanks for Health (BioHealth) established in 2002 (Stoltenberg et al., 2012). The consortium was presented as changing the Norwegian research landscape dramatically by advancing biobanking technologies, coordinating efforts in the development of biobanking tools and facilitating linkages between epidemiological research data and national health registries. BioHealth was eventually replaced by Biobank Norway, spanning even more biobanks, and importantly, a consortium providing 'internationally competitive biobanking services' (Stoltenberg et al., 2012, p. 136).

As with NBS, developments within biobanking have occurred rapidly over the past few decades, as local collections have grown into a global enterprise (Morente et al., 2008). Biobanks are currently presented as carrying an extraordinary potential, 'providing a backbone for unprecedented progress in human health worldwide' (Hewitt & Hainaut, 2011, p. 50). This is particularly true for biobanks containing genetic information, which have been elevated to the status of 'global public goods', a potential source of beneficence to all humans (Knoppers, 2005, p. 11). Despite this optimism, biobanking is an increasingly complex activity, accelerated by emerging technologies and scientific developments, and accompanied by new ethical challenges and a need for international collaboration and harmonisation. Among these challenges are, for example, the changing perceptions of the significance attributed to human samples and the ethical and legal bounds this imposes, and the balance between individual and societal interests in biomedical research (Morente et al., 2008). It is this complex situation future parents and their newborns are implicitly invited to join when accepting an invitation to NBS.

### **Newborn Screening in Norway**

Norway's national NBS programme began with two conditions, PKU and congenital hypothyroidism, in the late 1970s, and its panel has expanded twice since then. The first change, in 2012, took advantage of technological advances in tandem mass spectrometry allowing simultaneous detection of multiple metabolites using a single sample and expanded the screening panel to twenty-three conditions (Chace et al., 2003). It also imposed a six-year time limit on sample storage. This was due to concerns over the 'clear potential for misuse'<sup>1</sup> (Datatilsynet, 2011, p. 2) raised

during the public consultation: Norway had switched from the perishable capillary tubes to durable filter cards in the early 2000s, and the imposition of a time limit on storage was meant to secure privacy by preventing the inadvertent creation of a 'comprehensive' population biobank 'as a side effect' of the regulation's wording (Kirkerådet, 2011, p. 3). The most recent change, in 2017, coincided with a change to the law that mandated that the dried blood spots from NBS be stored indefinitely and effected major changes to consent practices. Implementation of these changes is ongoing. Participation in screening is virtually 100%.

In Norway, NBS is voluntary. Information to parents is given as a part of antenatal care, available online and in a leaflet produced in nine languages. The English version of the leaflet contains the following about parental consent: 'The procedure requires that the parents have received information about the screening and given their consent. Parents who do not wish to have their baby screened should notify the maternity ward staff' (Oslo universitetssykehus, 2019a, p. 1). In the hospital setting, consent is presumed, that is, the newborn is screened unless the parents object. For those who deliver outside the hospital setting or who are discharged before forty-eight hours after birth, taking one's infant to the hospital for screening is considered active consent. This procedure realises the primary purpose of the screening: early detection of disease.

The two-page leaflet also contains information about storage and use of blood samples and personal data, including options for parental withdrawal of the blood sample from storage and research, respectively. Opting out of these purposes requires giving notification to the unit for newborn screening, and parents are referred to their webpages. New online information in English provides links to additional ways of withdrawing consent (Oslo universitetssykehus, 2019b).

Between forty-eight and seventy-two hours after birth, a healthcare worker pricks the newborn's heel and collects drops of blood in circles on a filter paper card. Demographic information is added and the card is sent to the national NBS laboratory in Oslo, where the sample is tested for twenty-five congenital conditions. Most families will hear no more about their child's screening test, but around one in every 1000 infants tests positive for one of the conditions (Oslo universitetssykehus, 2019a, p. 1). In such cases, doctors at the NBS programme notify the infant's doctor and parents, perform confirmatory diagnostics and initiate early intervention and treatment that may save the infant's life or prevent severe, permanent disability.

A major transformation in the NBS programme occurred with a change in the Norwegian Treatment Biobank Act in 2018. Prior to these legal changes, NBS had, for all intents and purposes, served only its primary and closely-related secondary uses. Technically, it was possible to access the biobank for research with ethics committee approval, either by explicit written consent or by waiver of explicit consent. But blood samples which were to be destroyed after six years were relatively uninteresting to genetic epidemiologists. Additionally, both the Regional Ethics Committees and the programme's advisory body positioned themselves as gatekeepers and restricted access to what screening personnel describe as scant residual sample material to research which could directly benefit the programme.

As a result, NBS blood spots were insulated from large-scale unrelated epidemiological research.

The legal changes meant the storage time for the samples changed from six years to forever. Furthermore, the law now explicitly makes available biological material from NBS for medical research in accordance with the rules in the Health Research Act (again, this was possible before, but expressed only implicitly). Consent procedures were changed simultaneously, requiring that parents be informed of storage and research, and the option of withdrawing consent both at birth and again one to two years later, and that the adolescent screened as an infant be informed of the option of withdrawing consent when they turn sixteen, the age of medical majority in Norway (Lovdata, 2018, § 9 a). One effect of these changes is that whereas prior to the change only families with an infant testing positive for a screening condition would have contact with the programme after the initial screening test, now each family will be contacted by the NBS programme at least three times. Ways of managing this contact and facilitating consent and withdrawal are still being developed. The other major change is that the residual dried blood spots stored in the NBS biobank, once reserved virtually exclusively for research that would serve the purposes of newborn screening (Oslo universitetssykehus, 2019c), are now stored forever and legally regarded as equivalent to any other sample in the treatment biobank, lowering—at least theoretically—the threshold for unrelated secondary use. This we regard as an instance of function creep, to which we will soon return.

### **Secondary Use of Samples**

In this article we analyse recent changes in the storage and potential for secondary use of blood spots from the Norwegian national NBS programme. Secondary use, for the purposes of this article, is any use beyond the initial newborn screening; use with potential benefit for citizens other than the children being screened. We understand ‘closely-related’ secondary use to encompass use of dried blood spots for purposes directly related to NBS: for example, quality assurance, methods development and research related to new conditions for which newborn screening might be relevant in the future. All other objectives fall into the category of ‘unrelated’ secondary use (Friedman, et al., 2017; Nordfalk & Ekstrøm, 2019). Accommodating any type of secondary use requires that samples be stored after the primary screening purpose has been met. The mere fact of storage provides a logistical opportunity, if not a regulatory one, for unrelated secondary use. This opportunity is not exclusive for NBS samples but is true for all collections of stored biological samples and the list of documented and hypothetical secondary use is extensive (O’Doherty et al., 2016). Regulation and practices vary both between and within nations, and controversy prevails over which forms of secondary use are acceptable (Kharaboyan et al., 2004).

For the purpose of this article we focus on the secondary use legitimated by the latest changes in Norway’s NBS programme, making its biobank more suitable, as well as explicitly available, for general research purposes.

### Approach and Methods

Drawing on the theoretical concepts of ‘function creep’ (Dahl & Sætnan, 2009, Duster, 2008; Fox, 2001; Marx, 2005) and ‘scientific citizenship’ (Elam & Bertilsson, 2003; Irwin, 2001), and using data collected as part of the project ‘Developments in newborn screening in Norway’,<sup>2</sup> this article examines the implications of recent changes in NBS for the infants who are, or have traditionally been seen as, screening’s primary beneficiaries. We argue that explicit sanctioning of the use of NBS samples represents an instance of function creep and discuss how these changes may affect the citizenship of coming generations of Norwegians.

Our project is a situational analysis (Clarke et al., 2018) of the ‘newborn screening in Norway’ arena (Clarke & Star, 2008; Strauss, 1978). In the project, we analysed the public consultation documents, parliamentary committee hearing and parliamentary debate in the newborn screening case using the positional mapping techniques from situational analysis and Prior’s (2003) document analysis. We also conducted semi-structured qualitative interviews with participants with specialist knowledge of different aspects of our ‘situation of inquiry’. These too we analysed using the tools of situational analysis, identifying positions (not) taken and discourses represented.

So far, we have introduced the situation for biobanking and NBS, discussed secondary use and presented our study and research methods. We now examine our key analytic concepts in greater detail, before relating the process by which the NBS programme changes were effected and discussing the pressing questions these changes raise.

### Key Analytic Concepts

In this section we present the concepts of ‘function creep’ and ‘scientific citizenship’, which inform the analysis that follows. Function creep is a term which describes a process whereby things acquire new applications not originally intended or foreseen at the time of their creation. Synonyms include surveillance creep, control creep, data repurposing and secondary use (Dahl & Sætnan, 2009; Duster, 2008; Fox, 2001; Marx, 2005; O’Doherty et al., 2016). The trajectory for function creep tends toward increasing inclusivity: of targets, scenarios and legitimate(d) uses (Williams & Johnson, 2005). The bulk of the literature on function creep, surveillance creep and control creep is found within the fields of surveillance technology, law, criminal justice, security and privacy. In these domains, discussions of function creep are often linked to issues of governmental or institutional overreach. Meanwhile, the literature on data repurposing and secondary use tends to be found in the context of personal health data and the focus is more often on the ethical (re)use of existing data. Dahl and Sætnan (2009) acknowledge a preponderance of negative implications associated with surveillance and control creep and favour the more neutral term ‘function creep’:

‘Creep’ can refer to a secretive, sneaky process of change. How democratic or undemocratic the function implementation process has been may also be linked to the outcomes—how we see a given function as affecting distributions of power, autonomy, knowledge, access to resources. But the term may also simply refer to slow, crawl-paced change, which may be a good thing as it allows time for reflection, debate and democratic process. (Dahl & Sætnan, 2009, p. 85)

In its most innocent variations, function creep may facilitate creativity, innovation and even public health. Unchecked, however, function creep may change the significance of a piece of personal data from benign, documentary information to justification for a denial of rights. O’Doherty et al. (2016) warn that it is naïve to imagine that today’s political situation is static and that one must reckon with evolving political and legal climates facilitating the repurposing of personally identifiable data. Along with Dahl and Sætnan (2009), and Marx (2005), they call for reflection on the potential long-term consequences of data repurposing and the development of pre-emptive strategies to manage function creep. Marx cautions:

Asking questions about the process of surveillance creep and possible latent goals should be a central part of any public policy discussion of surveillance *before* it is introduced. Beyond determining if a proposed tactic is morally and legally acceptable, and if it works relative to alternatives and can be competently applied, it is appropriate to ask, once the foot is in the door, where it might lead. (Marx, 2005, p. 387, emphasis in the original)

Both surveillance and medicine have a black box quality. They have in common that they employ large amounts of sensitive personal data in ways and for purposes not easily articulated by lay citizens. Concerns over privacy are similar for both, perhaps especially when the collection of medical data is performed by a government entity (Knoppers et al., 2012).

Public health initiatives like NBS and cancer screening generate vast amounts of data. O’Doherty et al. (2016) point out that the very existence of data repositories invites their creative exploitation and that while public health repositories like NBS are obvious targets for repurposing, even personal data from seemingly innocuous sources, such as fitness trackers and other wearable devices, can be appropriated for purposes beyond the original scope of their collection. While some have argued that it would be unethical not to use or to allow the use of such data to improve public health, this remains a contested question (Harris, 2005; Shapshay & Pimple, 2007). Here, we reflect upon the changes in the secondary uses of Norway’s NBS programme in terms of function creep, discussing them in an active, processual light, exploring how the changes occur and examining their potential consequences.

Our analysis also draws on notions of citizenship, as both medical screening and medical research are framed by discourses on the relationship between individuals and society. In sociological theory this relationship is approached through different theoretical perspectives on citizenship, like biological citizenship



(Rose & Novas, 2005) and scientific citizenship (Elam & Bertilsson, 2003). Acknowledging that both could enlighten our analysis, we have chosen to apply the latter, as the observed function creep clearly points in the direction of challenges related to changes in Norwegian legislation that will make engagement with science an imperative part of virtually every future citizen's personal life.

Treating the democratisation of science in an early account of scientific citizenship, Latour (1998) explores the 'New Deal between research and society', which he aptly brands a 'collective experiment', indicating that we all have some role in the production of new scientific knowledge, whether as observers or the observed. He posits that research and society must become increasingly 'entangled' in the future in order to solve the increasingly complex problems of the day. The image of our common entanglement in a collective experiment underscores the 'messiness' inherent in democracy's attempts to keep pace with research situations in constant, rapid change.

Citizens' scientific engagement can take many forms and happen at different levels. Elam and Bertilsson (2003) suggest that citizens can be consumers or confronters of science, or engagers with science. Meanwhile Irwin (2001), Koenig (2014) and O'Doherty et al. (2011) cast citizens as co-producers of science, whose engagement with science through various advisory boards exemplifies the workings of deliberative democracy. Citizens' co-production of knowledge may also take the form of activism or advocacy, as seen in the fields of HIV and breast cancer research (Epstein, 1995; McCormick et al., 2003), or direct participation in biobank research (Tutton, 2007). Of note is that most of these forms of participation assume a competent adult or mature minor participant (see Knoppers et al., 2016). There are knowledge-production roles for those who lack the ability to participate fully in the activities of scientific citizenship, for example due to age, illness and/or intellectual capacity. However, these roles tend to be inherently more passive, demand less autonomy and afford less influence in relevant political decision-making processes. Individuals embodying these roles, for example, principally as subjects of research, constitute implicated actors (Clarke et al., 2018; Clarke & Star, 2008), whose voices are absent from or underrepresented in discourses which it must be assumed are relevant to their personal interests—current or future.

### **The Case: From Six Years to Eternity—Process and Arguments**

Returning to the Norwegian case, we apply these concepts to consider the significance of the changes to the national NBS programme. The crux of these changes can be summed up as follows: At a point when the programme wanted to expand the panel with two new conditions, it also sought an extension of storage from six years to ten, perhaps sixteen years, for purposes of quality assurance and follow-up, with subsequent sample destruction. When the draft legislation was published, however, the storage question had been foregrounded, the new conditions had become little more than an afterthought. The title read 'Proposed law regarding changes in the Treatment Biobank Act—permanent storage of blood samples in newborn screening, etc.' (HOD, 2017).



The (visible) political process by which permanent storage was effected consisted of a public consultation, a hearing in the Parliamentary Committee on Health and Care and a parliamentary debate preceding the vote. News coverage of the impending population-wide DNA biobank was scarce and there were no public debates on the proposed changes. Media coverage was largely confined to a series of skirmishes between professionals and politicians in the medical daily news website *Dagens Medisin*. In one, the Minister for Health and Care, Bent Høie, was quoted dismissing the fears shared by the Data Protection Authority, the Association for Medical Genetics and the NBS programme itself, among others, that a national DNA databank was on the horizon: ‘This is not a gene bank of Norway’s population, it’s a spot of blood on a piece of paper’ (Bordvik, 2017). Dr Asbjørg Stray-Pedersen, senior physician at the NBS programme and Chair of the Board for the Norwegian Association of Medical Genetics, trying to strengthen the case ‘against’ permanent storage, was quoted in the same article, disagreeing with Høie:

I have to correct Høie on one point. It is in practice a permanent national gene bank that is being established. Because even if it is only a spot of blood on a piece of paper, we can with today’s sequencing techniques use that sample to test the complete genetic material of the person, in only a few hours. And reidentification based on genetic data is simple. (Bordvik, 2017)

It might seem counterintuitive that scientists in the NBS programme and in neighbouring social worlds should argue ‘against’ a political initiative creating a population biobank based on NBS residual dried blood spots. While not rejecting the potential beneficence of secondary use of screening samples, those who opposed the legislation feared that conflating the objectives of screening and of research risked jeopardising public trust in the programme, high participation rates, and ultimately, infants’ health. Such a biobank, they argued, might be achieved independent of NBS and after thorough public debate.

### **The Public Consultation**

Other than these exchanges, public engagement with this process was limited to the public consultation, the timing of which was noteworthy: The consultation was published on 2 June 2017, with a deadline of 4 September for comments. Coinciding with the summer holidays, it seemed the consultation had been set to the time of year when people are least available. Positions taken in the consultation comments regarding what to do with newborn dried blood spots tended to align with one of two camps emphasising the importance of protecting personal integrity and trust in the programme, and the importance of securing the common good through research, respectively. The NBS programme itself did not endorse permanent storage of samples, hoping that children’s health would remain the focus of screening. The Norwegian Data Protection Authority pointed out that the white paper had failed to ‘clearly differentiate’ between primary and secondary use in the

government's justification for permanent storage, thus obfuscating the fact 'that the material will be very useful for medical research'. They also believed it failed to discuss the risks and ethical and privacy aspects of what would, in fact, become a DNA biobank of the Norwegian population:

We believe that the proposal does not adequately make visible which ethical and privacy-related questions must be discussed before a position is taken on whether we in Norway will allow the establishment of a national biobank with blood samples from the entire population. It is also our judgement that a risk analysis has not been carried out to identify possible negative consequences of allowing such a collection of biological material. (Datatilsynet, 2017, p. 2)

The Norwegian Institute of Public Health and the Norwegian Cancer Society, on the other hand, touted the potential in such a database for 'world class research' (NIPH, 2017, p. 2).

The law must be adjusted to fit the needs of the day, and not limit the possibilities for safe reuse of data in research analysis. It is therefore gratifying that the ministry suggests a relaxing [of regulations] that can result in better use of data to develop knowledge, while at the same time privacy is well safeguarded. (Kreftforeningen, 2017, p. 1)

These latter positions aligned with government strategy documents emphasising the economic potential residing in Norway's biobanks and health registries. Very few non-professional entities were represented in the consultation comments. The proposal in the consultation remained unchanged.

### **The Committee Hearing**

In January 2018, the Parliamentary Committee on Health and Care invited expert testimony at a hearing on the same proposal (Stortinget, 2018).<sup>3</sup> Represented were the Norwegian Cancer Society, the NBS programme, the Norwegian Association for Medical Genetics, The Norwegian Biotechnology Advisory Board, the Norwegian Data Protection Authority and the NBS programme's advisory body.

The Biotechnology Advisory Board called the initiative an attempt to 'sneak-introduce a biobank by suggesting that newborn screening [blood spots] be saved forever' and the medical geneticist took up considerations of biobanking versus security, reminding the committee that 'even if we all think that the future is bright and great and if we can just collect enough data, we will solve the mysteries of medicine, it should be allowed to be a bit critical to the argumentation' the government employed in the proposal when the result would be to 'build up a national gene bank. As a geneticist I need to point that out'. The Data Protection Authority decried the fact that 'such a wide-reaching proposal' was put forth 'without a proper evaluation, and without our having had a proper debate about

it', and drew a distinction between the gravity of the matter and the superficiality of its treatment:

And if we look at—and I spent a while on this yesterday—which important public debates have been the subject of their own Official Norwegian Reports the past few years: arming of police, the sharing economy, police special divisions, we studied the consequences of allowing stores to open on Sunday...but when we want to establish a national biobank, we sit here with a fourteen-page consultation from the Ministry and sixteen pages worth of proposed legislation, without having studied the problematic sides of this proposal at all. (Stortinget, 2018)

Of all the participants, only the Cancer Society were positive about permanent storage, basing this support on the need to develop better medicines. In this exchange, we find complementary and competing discourses like medical optimism, precautionary ethical principles and appeals to political duty and to logic. We read this opposition, which is consistent with positions taken throughout the legislative process, as an effort to preserve what it was feared might become a tenuous public trust in the programme. The overriding message was not that biobanks are bad, but that if done, they must be done in the right way. The proposal was sent unchanged from the committee to parliament for debate. Two months later, after less than an hour's debate, parliament passed the proposed changes.

The traces of scientific citizenship in this process are scant, limited to consultation comments from a few patient organisations. In this sense, the Norwegian populace have remained subjects rather than citizens. The outcomes of the process may, however, drive a change in this status, as future generations will now be obliged to deal with concrete questions hitherto reserved for the clinically-affected few. Given the potentially far-reaching implications of the changes to the NBS programme, we now turn to a closer discussion of these changes as they pertain to the fusion of NBS and biobanking in Norway.

### **Discussion and Conclusion: Infants as Scientific Citizens**

NBS in Norway has, so far, been an offer that very few parents refuse. This may partly be explained as the outcome of great public trust in the screening programme, but it may also reflect an informed consent procedure bordering on parental assent. As such, there is little citizen deliberation around participation in the programme. Furthermore, there are strong indications that the Norwegian population have great trust in regulations, ethical boards and researchers in matters of both screening and biobank research. This is exemplified by biobank donors expressing trust in the HUNT Biobank despite not being able to state what they had consented to when donating (Skolbekken et al., 2005) and viewing commercial use of biobanks as acceptable providing it promotes the common good (Steinsbekk, et al., 2013), as well as by women participating in the national mammography screening programme (Solbjør, 2008).

From society's perspective, both NBS and biobank research are sound investments in future, healthy citizens. By changing the storage period of biological samples from six years to eternity and making the stored samples available for non-clinical research, the potential in this societal investment surges. The realisation of this potential depends on many factors, but we will concentrate here on those believed to influence trust in the new format of the NBS programme. A basic assumption is that nothing should be undertaken which could jeopardise the trust hitherto placed in the screening programme or arouse fears over the potential for misuse, as we have mentioned earlier.

A pivotal part of the new format is the requirement for recontact with the opportunity to withdraw consent. In the past, it has been regarded as a mark of the success of the screening programme when only families with screen positive children are contacted, as this indicates a low false-positive rate. It remains to be seen how increased awareness of screening and biobanking will affect public perceptions of the programme. It is still early days for the introduction of this scheme, which means that the effects of the function creep are uncertain. Below we will look at some of the issues that have to be dealt with if negative consequences for the NBS programme are to be avoided.

A likely development in coming years is a transformation in the construction of children from being a vulnerable group in need of protection to a group representing a resource to society from the very beginning of their lives. Recently, their blood has been compared to Norway's new oil (Time, 2017). In general, it is recognised that young children should not be subjected to the same responsibilities as adults (United Nations, 1989, Articles 32 & 38), but that they nevertheless are entitled to the benefits of infrastructure and security long before they are able to make their own contribution to society. In particular, children have hitherto been considered vulnerable and in need of particular protection in research settings (World Medical Association, 2013). Recent developments indicate that preparations are made that will make children scientific citizens from birth and even earlier in their existence, like the guidelines on the use of genetic testing of humans in medical and health research by the National Committee for Medical and Health Research Ethics (NEM, 2016), allowing genetic research on samples from children, provided an option for disclosure of 'actionable' genetic information is given. It is paradoxical that the adult scientific citizens described in Irwin's (2001) and Tutton's (2007) work, already capable of performing the responsibilities as well as enjoying the rights of citizenship, should be given all the wide-ranging protections of research participants (e.g. informed consent, access to withdrawal), while infants are constructed as contributing citizens without these protections from their first day of life. While it might be argued here that these protections are intact, with parents acting as moral agents on behalf of the infants, it could also be countered, in light of their future autonomy, that this still leaves them, at least in principle, more vulnerable than if they were to make their own decisions as adults.

Norwegian society now has a decade to prepare the first group of adolescents to make up their mind about confirming parental consent or opting out of the

biobank. In the US, the issue of raising genomic citizens has been addressed by educating adolescents to prepare them for receiving information from secondary genomic findings (Sabatello & Appelbaum, 2016). Similar issues will have to be addressed in Norway, perhaps leading to a new rite of passage wherein religious confirmation rituals are supplemented or replaced by rituals acknowledging the adolescents' inclusion into scientific citizenship. If Norwegian society desires this degree of participation from its youngest members, then equipping young scientific citizens to navigate a lived experience so steeped in complex and deeply personal information must be a societal responsibility. The science curriculum for Norwegian adolescents will likely have to span such issues as the interpretation of genome-wide sequencing results, understanding medical risk and incidental findings. There are challenges ahead that imply epistemic, emotional, relational and moral consequences, as already experienced by patients in clinical settings (Høyer, 2016). A consequence of the 2018 changes in legislation is, however, that these experiences will affect a substantial number of the members of future generations.

There is also a strong indication that function creep works in both directions: screening programmes become co-opted by research interests, and then the return of results from genetic research turns the research into a form of screening when a result is seen as actionable. We see the normalisation of this type of interaction with science as just one example of the increasing biomedicalisation of life and technoscience's transformation of our individual and collective identities (Clarke et al., 2003).

Much of what has been presented above depends on how the role of scientific citizen plays out in the future. As large-scale research efforts increasingly shift away from direct intervention with research participants to analysis of their biological materials and personal information, the nature of the risk to which the participant is exposed changes, and new ways of contemplating risk, harm, privacy and autonomy are needed (Eriksson & Helgesson, 2005; Melham et al., 2014; Ursin, 2010). The UN Convention on the Rights of the Child makes clear that children are to be protected against 'all other forms of exploitation prejudicial to any aspects of the child's welfare' (United Nations, 1989, Article 36). This quite wide-ranging protection anticipates ways yet unforeseen in which children may be exploited. Whether the storage of blood from individuals in an entire population constitutes or could in the future constitute exploitation, and what the nature of this might be, remains an open question. Certainly, the potential exists. Society is forced to find answers to the questions of what the rights and responsibilities of its youngest, most vulnerable citizens should be and how it can avoid jeopardising children's open future.

Theoretically, there is yet much potential in terms of exploring scientific citizenship both as a collaborative, meso/macro-level political exercise and simultaneously as a set of individual rights and responsibilities. Without focus on the latter, we risk overlooking the real consequences of scientific citizenship especially for members of vulnerable, implicated populations, whose concerns can be marginalised when they are measured against the majority. As the pendulum swings from individual rights towards a science of the public good, as is arguably the case

with biobanking of population-based screening samples, participation becomes synonymous with solidarity and autonomy loses some of its significance. Those in a weak position to advocate for themselves must also have representation in endeavours of scientific citizenship, lest we inadvertently expose them to forms of scientific exploitation from which we would like to think we had distanced ourselves.

The function creep we have observed in Norway's NBS biobank was effected through a process marked by a lack of public deliberation and by the selective suppression of voices sceptical of the establishment of a population biobank as a self-evident good, as well as the absence of voices representing infants' interests in terms of citizenship. The question of competent, adequate, disinterested representation for silent and implicated populations is a challenge with which just scientific societies must grapple. Not doing so risks undermining democratic principles by exploiting vulnerable individuals in the name of the public good and the advancement of scientific knowledge. Such pitfalls can be averted, however, by further cultivating democratic practices of open dialogue and debate, securing adequate representation for implicated populations and tolerating the uncertain outcomes of democratic deliberation.

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#### **NOTES**

1. All translations from Norwegian were performed by the first author. Where available, names of institutions, political documents and processes are taken from the relevant entity's own translated materials.
2. Study approval by the Norwegian Centre for Research Data (NSD), Case Number 52064.
3. All direct quotations in this section are translations made from the first author's transcription of the official video file (see Stortinget, 2018).

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