Special Section: The Power of Choice:
Autonomy, Informed Consent, and the Right to Refuse

Should Parental Refusals of Newborn Screening Be Respected?

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Introduction

For over four decades, knowledge that symptoms of some inherited diseases can be prevented or reduced via early detection and treatment in newborns has underpinned state-funded screening programs in most developed countries.[1] Conditions for which newborn screening is now a recognized preventative public health initiative include phenylketonuria (PKU), congenital hypothyroidism (CHT), and, more recently, cystic fibrosis (CF) and sickle cell disorder (SCD). The use of tandem mass spectrometry to detect conditions such as amino-acidopathies and fatty-acid oxidation defects is also becoming increasingly prevalent.[2]

The early identification of children who are at risk for these conditions can have very positive implications. To take the most significant example, a child born with mutations that would otherwise lead to symptoms of PKU will have a vastly different kind of life if the condition is detected in early infancy rather than later. The introduction of a modified diet at this time, although cumbersome, will prevent the onset of severe mental impairment, allowing the child to lead a virtually normal life.[3]

Although clinical indications are sometimes more contentious when justifying screening for other conditions, by and large newborn screening is clinically valid and carries only minimal risk. However, it is sometimes declined by parents, presenting healthcare professionals with an ethical, legal, and practical dilemma. Consider the following scenario: Emma and Tom both work as pediatricians in a large city hospital. They have recently had their third child, a daughter named Clare. During a postnatal visit to their home by a midwife, Emma indicates that she and Tom do not want Clare to have any newborn screening. Emma reports there is no family history of any of the diseases being screened for, and she feels strongly that the probability Clare will have any of the conditions is so low that it cannot justify subjecting her to an invasive test.

This scenario gives rise to three issues, each addressed below. First, is Emma and Tom's refusal of newborn screening for Clare justifiable? Second, should the law ever mandate newborn screening over parental objections? Third, how

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should such refusals be managed in practice? Using the example of PKU screening, it is argued that although refusals are often difficult to defend, legal intervention is unjustified as a means of compelling parents to allow their infant to be screened. Nevertheless, the state may be justified in exercising some degree of "influence" over parental decisionmaking, via the practices of health professionals involved in newborn screening.

It is important to point out that besides that in the above scenario, there are a variety of reasons why parents may decline newborn screening. Parents may not wish to know whether their child will become ill or whether he or she is a carrier of a recessive gene.[4] They may have particular religious or cultural beliefs condemning any invasive procedure on a child who does not appear to be ill. They may perceive that an earlier experience of screening with an older child was traumatic (via the procedure itself or perhaps through a false positive result). Parents may also decline screening because they do not want their child's DNA to be stored and used in future research or because they reject the increasing emphasis on genetics in modern society. A mother may decline due to a fear about the child's misattributed paternity being disclosed during subsequent clinical investigation.

Newborn Screening: History and Current Practices

The first newborn screening program, to detect cases of PKU, was initiated in many countries in the 1960s. Its purpose was to identify those with the condition and enable early dietary intervention before the onset of mental impairment. Screening for CHT was introduced in the late 1970s to early 1980s and CF screening has also been introduced in many countries since that time.[5] The diseases for which newborn screening is offered differ from country to country, based on the prevalence of particular conditions in any given population.

The significant resource implications of newborn screening necessitate that testing should only be performed when justified by sound clinical reasoning. In the United Kingdom, a key factor when evaluating the introduction of new tests for newborn screening is whether the test meets the National Screening Committee's *Criteria*.[6] Relevant factors include that the condition should be an important health problem with a well-understood etiology, the presence of an effective treatment or intervention, and evidence of ethical acceptability of screening to all stakeholders. Screening for PKU easily meets these criteria. However, screening for other conditions (such as cystic fibrosis) is more contentious, as there is disagreement within the empirical literature as to the value of early interventions.[7]

In the United Kingdom, newborn screening is offered to parents at a post-natal home visit when the infant is around six days old. A small blood sample is obtained by way of a "heel prick" test, which transfers the sample to a specially designed blood spot card (a "Guthrie" card). These cards are sent to a regional genetics laboratory for testing and "normal" results are given to parents at the six-week health check. Any putatively positive result is reported to the infant's family doctor without delay, to enable further investigation. Approximately 1% of the 600,000 newborns screened in the United Kingdom each year receive further investigation, but only around 250 of these babies will have one of the conditions being screened for.[8]

Parental Refusals of Newborn Screening

Parents Who Decline Newborn Screening

Uptake rates for newborn screening are generally very high, with more than 99% of parents choosing to proceed.[9] In the United Kingdom, parents are able to decline newborn screening with no repercussions, save for the returning of a blank blood spot card to the laboratory. In the United States, parents do have the right to opt out from otherwise mandatory testing, although it is debatable whether this option is actually given to parents in practice. The Irish High Court has upheld the decision of a couple who declined newborn screening.[10] Despite this right to decline screening, there is consensus among policymakers that screening should be strongly recommended to parents.[11]

In terms of absolute numbers of parents who decline newborn screening, few data are available. In England, screening is undertaken by separate regional genetics laboratories and data sets are not pooled. In the United States, a 1982 study of over 50,000 cases of newborn screening indicated that 27 sets of parents declined, a refusal rate of 0.05%.[12] In Scotland, of the 53,000 babies born there in 2003, the parents of 45 refused all newborn screening, and the parents of a further 16 babies declined testing for CF and/or CHT, but allowed PKU screening, an overall refusal rate of 0.116%.[13] The rate of refusals for 2003 showed an increase over previous years, perhaps attributable to the fact that 2003 also saw the introduction of written informed consent and screening for CF.

Informed Consent for Newborn Screening

The process of obtaining informed consent to newborn screening significantly varies within and between countries and has also changed over time. Newborn screening can either be performed after informed parental consent has been obtained or it can be mandatory. In some countries it is not strictly mandatory but has become so routine that parents rarely question or challenge the process, if indeed they are informed about it at all.[14]

In the United Kingdom, the past five years have seen a marked increase in health service expectations for informed choice and the right to refuse health interventions.[15] Indeed, the practice of screening in general has retreated from a "public health" model, which emphasized only the benefits of screening and had the central goal of high levels of coverage. Now, all screening programs are required (though not by law) to offer individual choice.[16] Individuals should have the opportunity to personally assess the risks and benefits of the screening program and should not feel they are being coerced into participation.

This change in emphasis is now reflected in newborn screening practices. The UK Newborn Screening Programme Centre, motivated by concern that limited or inadequate information invalidated consent for newborn screening, reexamined informed consent procedures and developed national policy.[17] The aim of the new procedures is to enable "process consent," the provision of high-quality information to help parents make an informed choice, while emphasizing that screening should be recommended.[18] Consent will be provided verbally.

In contrast to England, obtaining informed consent to newborn screening is virtually absent in the United States. In all but two states, testing is described as mandatory and is performed without parents' informed permission. Theo-

retically, parents are able to opt out of newborn screening, and parental education is encouraged.[19] However, information about screening is often not passed on to parents until after the blood sample has already been taken, usually in the neonatal nursery soon after birth.[20]

The practice of mandated newborn screening has been both lauded and criticized.[21] In favor of mandatory screening, Faden et al. have argued that to act otherwise would grant "parents the right to consign their children to a state of irreversible mental retardation" (p. 1397).[22] Against mandated screening, Clarke suggests informed consent helps foster trust in the healthcare system, notably the idea of "partnership" between parents and professionals in providing care for a child.[23] Friedman Ross contends that the obtaining of consent serves as a symbol of respect for the family and educates parents about the value and purpose of screening.[24]

Although the issue of mandating newborn screening is significant, it will now be put to one side. It will be assumed that parents do have the opportunity, one way or another, to intervene to decline newborn screening in their children. A tension thus arises between parental autonomy, children's welfare, and what constitutes reasonable state interference. To explore this, the three questions posed in the introduction will now be addressed.

Parental Refusals of Newborn Screening for PKU Are Unjustifiable

It is well understood that parents possess legal and moral rights to make a myriad of decisions for their children. Legally, parents can make decisions for their incompetent children (including medical decisions), so long as the decision is made with that child's welfare in mind.[25] Indeed, parental authority is usually only set aside in cases of emergency, parental abandonment, child abuse, or when life-saving treatment is being refused by parents.

Parents who decline newborn screening are unlikely to be classified as having abandoned or abused their children. Neither is newborn screening for PKU likely to be classified as a "life-saving treatment"; for children like Clare, there is no obvious indication that their lives are at risk. Refusing newborn screening does appear, therefore, to be within the scope of parents' legal rights to make decisions concerning their children's upbringing and healthcare.

Morally, perhaps the best expression to describe the rights that Emma and Tom have in raising Clare is "parental autonomy." Although less has been written about this concept as it applies to raising children (as opposed to reproductive autonomy), two themes are clear. First, the decisions parents make for children are significant and intimate to private life, as they comprise an important expression of values, preferences, and beliefs. Emma and Tom clearly have the right to express their autonomy and individuality in raising their children, a right against the state that should not be subordinated without due cause. To say otherwise would undermine the preservation of intimate family relationships.[26] Second, Emma and Tom's rights can also be underscored by their interest in *parenting*, a concept that has been discussed in some detail by Edgar Page.[27] This interest gives rise to their rights to make decisions according to their particular set of values.

However there are, of course, limits to these moral and legal rights, and they do not provide parents with a moral justification to act in any way they choose. The mere fact that a parent wishes to pursue a particular action in relation to

her child does not convey a right to act to bring this about. Parental autonomy is not absolute, as parents also have obligations to facilitate their children to grow, develop, and eventually exercise their own autonomy.[28]

Emma and Tom's rights to make decisions for Clare are therefore limited to those that further her welfare or the welfare of her family. For Clare, the significant potential benefits and minimal risks of screening for PKU would indicate that it is in her interests to be screened, and she will certainly not remember the slight trauma of the experience once she is older. Newborn screening for PKU (and some other conditions) offers an opportunity to obtain a clinically valid diagnosis with a low false negative rate. False positives are dealt with by way of immediate follow-up and reassurance. A confirmed positive finding offers the potential for earlier intervention and a consequent improvement in quality of life.

Feinberg is one who would be likely to support the position that parents should not decline newborn screening, at least for conditions where an intervention is available. In his writing on a child's right to an "open future," Feinberg recognizes the unique moral status of children and describes children as possessing "rights in trust," which have properties in common with autonomy-based rights of adults.[29] As children cannot exercise autonomy-derived rights until they are "fully informed and capable" (p. 25),[30] parents have an obligation not to let their values interfere with respecting what their child may want for her future self. Although we are usually bound to accept the autonomous but future-limiting decisions of competent persons (subject to Mill's harm principle), children's future autonomy should be maximized until they are able to make decisions for themselves. Otherwise, we risk violating their rights in advance.

If Clare were to develop PKU, her later ability to exercise the rights held in trust for her would be severely limited. Emma and Tom should therefore protect Clare's future and take all reasonable measures to prevent her from suffering irrecoverable harm. The absence of PKU in Emma and Tom's family history does not mean Clare won't be affected, and it also seems reasonable to assume that if Clare was able to make a decision as an adult now, she would follow the path that 99% of parents take and allow screening.

A further, broader argument can also be made that does not directly relate to the interests of Clare or her parents. Undetected conditions give rise to significant social resource implications. A UK healthcare trust that misses a case of PKU will bear the costs of that omission for the rest of that child's life. Although it would be Emma and Tom who take on most of Clare's day-to-day care should she develop PKU, the costs of medication, special education, and hospital services are likely to be significant, and resources are likely to be lost from other valuable ends (such as helping individuals whose diseases could not be predicted) as a result.

These arguments are, however, subject to two counterarguments. First, the claim that refusing screening is unjustified may smack of a state-imposed ideal of perfection, raising the problematic specter of eugenics. Invoking the claim that refusing screening is wrong could imply that parents' decisions should be subjected to validation, and any decision not in line with maximizing potential should be overridden. However, this is not so implied. Those promoting newborn screening do not claim that screening is designed to give rise to perfect children. Rather, a straightforward screening test can help ensure that a

child who may otherwise have suffered irreversible harm can lead a relatively normal and healthy life.

The second counterargument is that focusing entirely on Clare's current and future best interests overlooks the potential harm that Emma and Tom could suffer if a "false positive" result were returned, such as anxiety or hypervigilance about Clare's health. As described above, around 1% of newborn screens return an initially positive result, requiring further follow-up, although this is not described to parents in the United Kingdom as a "positive diagnosis."[31] Empirical studies have addressed this issue with respect to PKU and other conditions.[32] An early study described "PKU anxiety syndrome"[33] in which parents believed their child would develop mental disability despite a subsequent negative result. This was not, however, supported by data. Further studies have shown that parents report no adverse changes in their parenting behaviors or attitudes toward their children, although a minority do have lingering concerns about their children's health.[34] The prevailing opinion on this body of empirical work is that if appropriate kinds and amounts of information are provided to parents in light of an initially abnormal result, such harms should be minimized.[35]

Although not vigorous enough to defend all parental refusals of testing, these counterarguments do suggest at least one qualification to the above argument that declining newborn screening for PKU is unjustifiable. That is, the argument may not be applicable to instances of refusals of newborn screening for other conditions where the balance between the benefits and harms of screening might lean another way. Contrary to screening for PKU or CHT, where a refusal runs contrary to strong clinical evidence, Emma and Tom would be unlikely to place Clare at any increased risk if they were to decline newborn screening for Duchenne Muscular Dystrophy, where no intervention is possible to prevent the onset of disease.

The Law Should Not Intervene to Compel Newborn Screening for PKU

Most refusals of newborn screening are best viewed as a conflict between parental autonomy on the one hand and the future welfare of the child on the other. It has been argued above that Clare's future welfare should usurp Emma and Tom's parental autonomy to decline PKU screening. It is also important, however, to consider how this tension should manifest in light of what constitutes reasonable state interference in parenting.

Some have argued that legal intervention to compel newborn screening is acceptable, if not required.[36] However, despite the above argument that Emma and Tom's refusal is unjustified, it will now be argued that the state should not intervene to compel newborn screening for any condition, including PKU. The reason for this is that although parental autonomy is subject to the constraint of children's welfare, it also has an additional, counteracting element. Although parental autonomy is not, of course, legally or morally limitless, parents should (and do) enjoy a degree of freedom from state interference in private and family life. The moral obligation to agree to newborn screening for PKU does not follow on to a justification of using state powers to compel parents to undertake this moral act.[37]

Despite this counteracting freedom, the threshold for state intervention in parental decisions made on behalf of children remains poorly defined. Although

the state is precluded from interfering in parents' choices about their children's religious beliefs, there are laws in place to ensure children receive a minimal standard of education. Parents have abundant freedoms to determine what lies in their children's best interests, and they significantly shape what kind of person their child will become. Parents also have the liberty to undertake all kinds of arguably unethical behavior in front of their children if they wish to: They can smoke in front them, feed them the wrong kinds of food, and fail to encourage enough physical activity. And although we often wish that parents wouldn't dress their children in matching outfits or subject them to truly embarrassing pastimes, we do not interfere with their right to do this.

Several scholars have attempted to define this threshold in a more formal way. For example, Schoeman has argued that, in general, parents' decisions should not be supervened unless it can be shown that "the decision of the parents would seem to be from most perspectives to be shockingly reckless or negligent" (p. 58).[38] Given the intimacy of the family, with its own goals and purposes, there should be a high threshold of conditions breached (such as a serious violation of parental authority) before the state should intervene to protect the rights of a child. The abstract liberal principles of the state, although important, do not reach into the majority of intimate family matters. Although clinical expertise dictates that newborns should be screened for PKU, it is evident that those in positions of clinical responsibility and the courts do accept refusals of PKU screening, suggesting that Emma and Tom have not committed a serious violation of parental authority.

Goldstein cautions against two things: using the law as a blunt instrument for handling dilemmas of this kind and recognizing the importance of the fact that clinicians should not make value judgments in the place of parents when the child's life is not at stake.[39] Noting that the law has a strong presumption in favor of parental authority free from coercive state intrusion, he argues that the law lacks the capacity to supervise the delicately complex interpersonal bonds between parents and children. If death is not a likely outcome of the healthcare choice, he claims there is "no justification for Governmental intrusion on family privacy or overcoming the presumption of ... parental autonomy" (p. 664).[40] If a child's life could be at stake, then the law can only intervene in strictly defined circumstances, including agreement within the medical profession about an absence of conflicting medical advice about the need for the procedure. Although PKU screening is proven medically, the likelihood that Clare will suffer harm is low, and so Goldstein's threshold would not be met.

This suggests that Emma and Tom's refusal of newborn screening for PKU should not become subject to legal interference. To act otherwise would upset the finely drawn distinctions between state and parent-mediated decisionmaking for children that occur in practice. Their failure to have Clare screened, although placing her at increased risk, falls within the class of parental freedoms that, although potentially unethical, should not be regulated by law. Although most of us would regard these as being within the scope of parental obligation, we would feel most uncomfortable intervening with them any more strongly than the current encouragements bestowed on parents by the state. After all, society has a "tendency to conflate judgements about what is morally right and wrong with judgements about what are wise and defensible public policies" (p. 97).[41]

This argument for legal noninterference is not just about parental autonomy. Like parental autonomy, the concept of children's best interests also has a counteracting element, requiring that it not be applied ad infinitum to the detriment of other valuable ends. It is in Clare's best interests to belong to a family structure where Emma and Tom are able to make decisions for her. As the state cannot provide security or comfort for all children, a family (even with all the complications, imperfections, and difficulties that each is likely to have) provides the best environment for children's care and the development of cherished relationships. Mistakes are sure to be made, but children will benefit in the long term through being a part of a unit where a parent can make decisions. Therefore, arguments informed by best interests or the child's right to an open future must not interfere to prevent Clare from growing up in an effective and autonomous family environment.

Thus Emma and Tom's moral duty to consent to Clare receiving newborn screening does not provide a necessary or sufficient reason to give the arguments in favor of screening the force of law. Indeed, the right to decline newborn screening has already been upheld legally in at least one jurisdiction. In Ireland, the High Court has refused a request from a health board to mandate newborn screening for PKU.[42] In this case, parents had declined testing on the grounds that it was against their beliefs to inflict invasive treatment on a child. Although the case was decided on the terms of the Irish Constitution, some general principles also emerged. Specifically, although the state has a duty to protect and defend its citizens' rights, this duty is not unlimited. Families are in a special position as a natural, primary, and fundamental unit, whose rights will often be superior to those imposed by law. Courts should refrain from intervening in these kinds of parental decisions, even if parents appear to be acting wrongly or recklessly, so long as there is not a serious threat to the life or welfare of the child. Although a child's safety is important, this has to be viewed within the entirety of moral obligations present in society.[43] Risks of harm, particularly those with a low magnitude and likelihood, can be accepted to protect other values, such as parental autonomy.

This legal right to nonintervention in decisions to test children is not without limits, and courts will on occasion mandate that testing take place if the justification for testing was stronger. In the United Kingdom, for example, a court has ordered an HIV test in a six-month-old child born to an HIV positive mother.[44] However, such a case would be unlikely to arise in the absence of information such as the mother's positive status and so would be unlikely to be applied in circumstances of newborn screening for PKU, unless the parents were affected with or known carriers of this condition.

The law therefore stops at the doors of our houses, most of the time. And it should not enter to mandate newborn screening when parents decline. Intrusion into private life is improper, save for extreme circumstances such as a risk of death to the child or extreme welfare risk such as child abuse.

Managing PKU Screening Refusals in Practice

If what I have argued is correct, then parents should have the right to decline newborn screening free from state intervention, even though screening is the appropriate act from a moral perspective. However, one problem remains: the practical ethical issues involved in handling such refusals.

Presuming that current arrangements for carrying out newborn screening (at least in the United Kingdom) are retained, it will be health visitors or midwives who are presented with refusals of screening in practice. How should such refusals be handled? Although parents who decline screening should be offered information and counseling, it is also acceptable to exercise a degree of influence over parents' decisionmaking.

In the United Kingdom, the prevailing attitude of policymakers is that parents who decline testing should be provided with further information and an offer of follow-up counseling.[45] It should also be ensured that screening is not being rejected due to communication problems, such as language difficulties. However, parents should not be pressured to agree to screening.[46]

Policies such as this give rise to a conceptual difficulty. Parents are not to be pressured into receiving screening; instead they must be given the opportunity to exercise informed choice. Yet it is also policy that screening should be strongly encouraged in order to reduce the burden of disease. Attempting to marry these two policies is not easy and can lead to conflict. This conflict can be resolved by emphasizing one over the other, that is, justifying some degree of influence over parents' decisionmaking about newborn screening.

This assertion is contentious. If parents feel pressured to make a decision against their personal wishes, it could polarize their future attitudes toward healthcare. It is therefore important to distinguish how influencing parents' decisionmaking is not the same as coercing them into accepting screening.

Coercion can be defined as the presence of an unreasonable external pressure or constraint faced by a person when making a decision. According to Beauchamp and Childress, for coercion to occur there needs to be an intentional and credible threat of harm if a person does not decide in a particular way.[47]

An influence on parental decisionmaking about newborn screening is not a coercive offer of this harmful kind. Parents receive no threats of harm if they decline screening; indeed there are no repercussions at all, save for an offer of follow-up and the recording of a note in the child's health record for their future health observance. Influence could manifest merely as a bias toward presenting the positive implications of screening, albeit with open and honest counseling. Minimal time should be spent on the refusal process and policy but parents must know of their right to decline. The policy adopted in England, which does not involve written informed consent, easily accommodates the achievement of this kind of indirect and nonthreatening assistance with parental decisionmaking.

Therefore, rather than being concerned about the fact that the very existence of a screening program compels people to be tested, influencing decisionmaking instead provides a clear practical path for those implementing screening and can aid in the achievement of the dual ends of informed choice and promoting uptake. This will not limit parental autonomy in any practical sense, as refusals such as Emma and Tom's will still be accepted—they will just be encouraged to reason through their decision and listen to the evidence in favor of screening.

Care does, however, need to be taken when implementing this policy in practice. Providing the liberty to influence decisionmaking also does not condone the display of irritation or distaste at the supposed irresponsibility of the decision made. Further, the liberty to influence should not be translated as a duty to persuade.

Of course, the degree of influence that it is justifiable to exert over parents will vary inversely with the degree of effectiveness of treatment that is available. Midwives would be more justified in exerting influence over Emma and Tom's refusal of PKU screening than they would if they were to try and compel screening for CF or DMD, for example. Also if the likelihood of harm were very low (say, if a disorder had an extremely low prevalence, as is the case with some metabolic disorders), then again there would be less justification for influencing Emma and Tom to undergo screening.

Conclusion

In this paper, an argument has been advanced about the ethical, legal, and practical friction observed in parental refusals of newborn screening. The tensions between parental autonomy, children's welfare, and state policy can arguably be resolved via a respect for both the value of private and family life and the value of screening. It has been suggested that despite the fact that parental refusals of newborn screening may be morally unjustified, overriding parents' interests is very difficult to reconcile with the right to legal noninterference.

This belt of protection around parents' decisionmaking for children is clearly not unlimited. The argument certainly calls for some further analysis, which is beyond the scope of this paper. A principled account of parental autonomy is required—what kinds of acts or interventions might give rise to an absolute right to refuse state intervention, and which may only give rise to a prima facie right? This will ensure that the right to noninterference in decisions to decline newborn screening is not considered as a mere example of moral consistency within the context of current parental freedoms.

The argument against noninterference is, of course, also subject to empirical claims. For instance, a parent refusing newborn screening for a very low prevalence condition with an unproven intervention would be more justified in making such a refusal than a parent refusing screening for a high prevalence, catastrophic condition that is easily preventable. As newborn screening develops, the justification for refusals should be revisited, albeit within the practical confines of laboratory medicine.[48]

These tensions between parents, health professionals, and the state are certain to be brought into focus more acutely as genetic applications continue to develop and new methods of analysis emerge. Future technologies, such as whole genome sequencing, are under development and are already being considered by policymakers. It is therefore important to continually reflect upon these ethical, legal, and practical conflicts over time.

Notes

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4. This issue will arise particularly in screening for cystic fibrosis or hemoglobinopathies, where a "false positive" result discloses that the child is a carrier of the condition. In England it is standard practice to report this result to parents.
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