

in that case

A Lead Maternity Carer (LMC) is discussing newborn health checks with a pregnant woman and her partner. The LMC tells them that one of these checks is the Guthrie test, which is normal practice in screening for newborn metabolic disease. The LMC tells the parents that the Guthrie test involves a heel prick when baby is two to three days old and collection of several drops of blood on to some collection paper (the Guthrie card), which is then sent to the National Testing Centre to be tested. The remaining blood is normally then stored indefinitely, but the parents could opt for no storage if desired. One of the most common conditions tested for in using the Guthrie card is congenital hypothyroidism which occurs in one in every 4,500 babies in New Zealand. If not treated within the first weeks of life it leads to cretinism – severe irreversible developmental delay. Without newborn screening a diagnosis of congenital hypothyroidism may be difficult and delayed. The other conditions tested for are much rarer (except for cystic fibrosis) and are usually managed with special diets.

The parents inform the LMC that they do not believe in any blood tests for their baby and will opt not to have the procedure (they have also refused Vitamin K commonly given to a baby by injection immediately after birth to prevent newborn bleeding). They do not want anything that might be painful for their baby. The LMC is concerned about their response and has always wondered if this is one test that should be mandatory.

response

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This ethical debate is regularly posed for an LMC, and the situation outlined presents a response that is not uncommon from parents facing the responsibility of making decisions on behalf of their baby. The health professional can often face the debate of individual rights versus best interests. Within this debate is the added philosophical question of who is responsible for the health of a baby – the parents or the health professional?

The LMC can take some comfort in that legislation, contracting requirements and professional standards give some guidance.

Parents have the ‘Right to Make an Informed Choice and Give Informed Consent’ (Right 7, of the Code of Health and Disability Services Consumers’ Rights). Within this (paragraph 7) it is clearly stated that ‘Every consumer has the

right to refuse services and to withdraw consent to services’.

The *Human Rights Act 1993* clearly states that discrimination is prohibited against a person in regard to ethical belief.

Section 88 of the *Maternity Services Notice* in Section 4.5.2 Services Following Birth, requires that an LMC ensures ‘provision of or access to services, as outlined in the Well Child Tamariki Ora National Schedule’. When we look at this schedule it clearly states, in relation to Vitamin K ‘... discuss requirements and options with parents’. The newborn metabolic screening section states ‘the LMC is responsible for ensuring this screening procedure is undertaken’. However it also states that the LMC should ‘gain informed consent of parent’.

With respect to the case, the question arises as to whether Informed Consent has been achieved. The issue of not causing pain to the child is a normal parental response but is this reason enough, given the possible consequences of this decision, to reassure the LMC that the parents understand their responsibilities in regard to refusing the test? Further discussion with the parents is necessary, including giving a statistical explanation about incidences of disease and what these diseases are. These need to be described to the parents in a manner that assures the LMC they comprehend. If the parents cannot articulate the appropriate level of understanding and awareness of the implications of their decision prior to consent, then their LMC will carry the responsibility for any untoward outcome. It is essential for the LMC to ensure the parents understand all of this when the decision is made.

This is the ‘informed’ part of ‘informed consent’, for which the health professional carries accountability. If the LMC is a midwife, the professional expectation is that the services are provided in partnership.

Standard One of the profession’s standards states ‘The midwife works in partnership with the woman’. Within this standard there is discussion about individual and shared responsibilities and that open interactive communication is necessary to negotiate choices and decisions.

This relationship makes it easier to explore the concerns of the parents. Whatever the decision at the end of this discussion with the parents, the LMC will be more likely to advocate for

the parents’ final choice with some confidence, as she will understand how they reached this decision.

However the question of the difference in belief systems between the LMC and the parents that is outlined is also difficult. The couple stated that they ‘did *not* believe in *any* tests for their baby’. This needs to be explored in depth by the LMC. As a result of this stance the health professional may find herself at complete odds with the parents. If she is to work in partnership the LMC will need to work with them to have an understanding of their values and they of hers. To uphold a belief system different from one’s own is difficult especially when an LMC is placed in the position of advocacy for the couple, should complications arise and decisions become challenged.

The LMC does have rights to express concerns and outline difficulties to the parents in regard to their decisions. Indeed to work in partnership with mutual respect requires this depth of mutual understanding. However the parents do have the right to receive care free of discrimination for an ethical belief that is different than the societal or personal belief of another.

The LMC, at the end of further discussion, must feel reassured with whatever decision is finally made is an informed decision free of coercion.

Documentation is essential to outline that the legislative principles have been explored in these circumstances should a negative outcome occur.

Again the midwifery profession’s standards can be referred to. Standard two states that ‘the midwife upholds each woman’s right to free and informed choice and consent throughout the childbirth experience’. Within this standard there is discussion about sharing all relevant information and facilitation of decision-making without coercion. It also states the need to respect the woman’s right to decline treatments or procedures but also to state clearly when the midwife’s professional judgement is in conflict with the decision or plans of the woman.

So where does that leave us, when we consider all of the above? Parents’ refusal to allow administration of Vitamin K is not uncommon. Refusing the Guthrie test is less common. The reality is that parents are entitled to refuse consent to these

procedures. Embedded in our health culture we have the rights and responsibilities of both consumers and health professionals with respect to issues concerning consent to tests and investigations.

The biggest factor in the scenario is not that the LMC is concerned about their response – that is a parent’s right. It is that the reason the parents have given so far is that they ‘do not want anything that might be painful for their baby’.

This is a natural response for parents. As a society we expect parents to be nurturing, protective and loving of their newborn baby. However, the response also suggests that perhaps the parents have not received sufficient information in language that they understand. Vitamin K can actually be administered in the form of three oral doses if having one intramuscular injection is unacceptable to parents. This is not mentioned in the scenario. Were the parents aware of this option when they refused Vitamin K? What information have they actually received on which to base their decision?

Parents who refuse Vitamin K for their baby have a right to receive full information upon which to base their decision. Oral Vitamin K may be more acceptable to the parents of this baby.

The Guthrie test on the other hand can look very traumatic for a baby. It does not state that the parents are refusing the test because of any opposition to what the test may detect, treatment options etc.

This needs to be explored further with the parents as there are a number of things an LMC could do that may reassure the parents about the *actual* taking of the test, e.g. introduce the parents to someone whose baby has recently been tested to discuss with them how their baby reacted. If the parents still refuse, that is their right but only when the LMC feels confident that all options have been offered and explained and that the parents understand the potential implications of the choice they have made.

Parents are responsible for their children and under legislation can make decisions on their behalf. Our responsibility as health professionals is to ensure that parents have sufficient information and the opportunity to discuss the options with us. It is then their decision. We will also face ethical dilemmas such as this regardless of whether or not these tests/treatments are mandatory. The decision to make tests mandatory does not free us from ethical debates – it merely changes the focus. Ethical issues will always provide a challenge for those working in health.

response

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Newborn baby metabolic screening was established in New Zealand in the 1960s and brought together into a national service (the National Testing Centre, NTC) in 1969. Seven conditions are tested for including phenylketonuria (PKU) and, as mentioned in the case, hypothyroidism. Similar programmes exist in most other countries including the UK, Australia and the USA.

What are the benefits of screening for these conditions? As discussed in the case the major issue is that diagnosing these conditions early without screening is difficult. Even short

delays can lead to significant and irreversible intellectual retardation, and other serious medical problems. With screening the diagnosis can be made within the first few weeks of life, special diets or medications commenced and all symptoms avoided. The conditions are not common, but a total of at least 30-35 babies will be diagnosed with one of the disorders each year in New Zealand. In addition to these benefits the heel prick blood tests are cheap and accurate.

Are there any real or potential disadvantages of newborn baby metabolic screening? As the parents in the case say there may

be some pain for the baby while the heel prick is being undertaken. However, this is usually minimal and can be reduced further with careful attention to technique and soothing strategies, such as allowing baby to breast feed during or immediately after the test, or the use of sucrose solution as an analgesic. Long term complications from heel prick blood taking are virtually unheard of.

As with all screening programmes newborn baby metabolic screening cannot claim to be completely accurate. However, it does come closer to this than most other screening programmes, with the chance of missing one of the conditions in a screened baby virtually zero, and the chance of incorrect diagnosis on the initial sample much less than 5% for most of the conditions (NTC Report, 1996). This does mean that some families will be asked to provide a repeat sample which will later reveal that their child does not in fact have one of the conditions (an initial false positive result). This is likely to generate short term anxiety and there is a possibility of more persistent effects on the parent child relationship.

Results of research in this area remain inclusive, and it merits further study (Fyro and Bodegard, 1987; Sorenson *et al.*, 1984). Literature regarding genetic testing of adults does suggest that carefully explaining the potential need for a repeat sample can minimise any psychological distress and there is no reason why this should not also be important in newborn screening (Marteau and Croyle, 1988).

Finally, some people are concerned about storage of Guthrie cards at the NTC and potential use of the sample after the test has been done. Cards are stored largely to investigate any cases missed by the programme and refine current testing procedures. Any other use of the cards without consent of the person from whom the sample was taken or their family is strictly regulated and occurs extremely rarely. Further discussion of this interesting issue is outside the scope of this commentary but these concerns cannot be a valid reason for refusal of newborn screening as long as parents are informed that they have the option to request return of the test card (Webster, 2001).

From this discussion of the facts relating to newborn screening it seems reasonable to conclude that the potential benefits of screening outweigh any associated risks. This is a view that seems to be shared by health professionals and the vast

majority of parents. (In 1996, approximately 98.4% of babies had a sample collected for newborn baby metabolic screening (NTC Report, 1996).) If parents refuse testing they may consider they are acting in the best interests of their child, but they're doing so on the basis of beliefs that are contrary to widely held and rational views. In cases such as the one described the first step should clearly be more detailed discussion with the parents to ensure they fully understand all aspects of the newborn screening process. In this particular case the parents are concerned about painful experiences for their baby: this type of protective response toward one's newborn child is clearly beneficial in many circumstances, and should not simply be dismissed. It's possible that with careful discussion of how short term pain may be balanced against very serious long term consequences for their child these parents may change their minds.

However, if their beliefs remain the same, should they have the right to refuse testing? Put in the very bluntest of language, should parents have the right to consign their child to a risk of irreversible intellectual handicap? We generally accept that parents have the right to make decisions regarding their child's care. This type of parental consent is, however, quite different from that we ask of adults: we are not primarily protecting the autonomy of parents, but instead we are using the parents' decisions because we believe they are their children's most conscientious advocates and have their best interests most accurately in focus. In addition, we want to protect and acknowledge the importance of families. However, sometimes parents' rights are overridden. If it's clear that parents are not acting in the best interests of their child, as in cases of child abuse, it's accepted that the child should be removed from their care. If there's doubt as to whether parents are acting in the child's best interests, application may be made to the court to override the parents' decision. This has occurred a number of times over the last decade in New Zealand, mostly relating to parental refusal of conventional treatment for childhood cancer. In addition to these medical situations we also oblige parents to provide their children with 'the necessities of life' and other aspects of life we consider important, such as education.

Does newborn baby metabolic screening fall into a category whereby we should override parental refusal? A small number of parents do refuse newborn screening each year but this has not come before the courts in New Zealand. The same issue

was recently considered by the Irish High Court and the Supreme Court of Ireland after the North Western Health Board challenged the decision of parents to refuse PKU testing for their son. Both courts found in favour of the parents, citing lack of any specific legislation requiring newborn screening and the considerable importance placed on family autonomy in the Irish constitution (North Western Health Board v. H.W & C.W., 2000). As in Ireland, there is no specific legal requirement for babies to undergo newborn screening in New Zealand. This is in contrast to the situation in the United States, where newborn screening must be offered to, and is legally required from babies in most States. (Although in 27/51 states parents may refuse testing on religious grounds (Mandl *et al.*, 2002).)

So, the concerns of the midwife in our case are viewed differently from country to country. In New Zealand the issue has not really been fully debated, perhaps because the screening programme operates extremely effectively and there are few refusals. However, the successes of the programme shouldn't lead us to be complacent, and we should give some consideration to how, as a society, we see best to deal with parental refusal of this type of screening. While it's certainly true that most babies screened are healthy and there is a low risk of actually having one of the conditions, the consequences

of missing the opportunity for early intervention are extremely serious. If we aim to serve the best interests of children then perhaps screening should be mandatory. If we want to promote parents' rights to refuse screening, then we must accept that this may come at considerable cost to some children.

References

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response

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Over the last decade New Zealand has moved towards a 'consumerist' model of health provision. There is an expectation that people (consumers) will make a rational choice of health care interventions from the range available, and that providers of these services will provide sufficient information to the consumer to enable an informed choice to be made. There is an increasing focus on consumers' rights, and a much better informed public is more frequently questioning health providers.

As a result of the increasing amount of health information available to the public, and the expectation that parents will

actively choose which interventions are provided to their children, there has been a rise in the number of parents who decline to consent to their child's participation in preventive healthcare. Immunisation surveys have always shown that a few percent of parents are 'active decliners'. However anecdotal evidence and some small surveys suggest that increasing numbers of parents are declining not only immunisation, but also other preventive healthcare procedures for their infants and children.

This case raises issues that are common in clinical practice, and in most situations the parents and clinicians come to an

agreement, which is the best for that child within the context of the family. If the matter is not one of life or death or serious threat to well-being, the provision of good information, advice and support usually leads to a satisfactory outcome. However, if parents refuse consent to treatment and the child's chances of survival are compromised society expects health professionals to act in the best interests of the child. Under the Guardianship Act an application can be made to the Family Court or the High Court for guardianship orders to be made in favour of the Court. This section is used from time to time where parents refuse to consent to treatment essential to saving a child's life.

The Court decides such cases using the best interests of the child as the overriding principle. In some cases the best interests of the child may not require lifesaving treatment to be provided. In *Re T* [1997] 1 WRL 242 parents of a child with a congenital liver defect declined consent for a transplant operation against medical advice. The Court of Appeal decided that the child did not need to have the operation on the basis that 'broader grounds than that of clinical assessment of the likely treatment' should be weighed 'in the balance of reasons against the treatment'.

However these are rare cases. Modern health care places an increasing emphasis on prevention, and screening programmes and preventive interventions are now offered to every child born in New Zealand. Neonatal screening for some congenital metabolic diseases and the provision of Vitamin K to prevent Vitamin K dependent bleeding (VKDB) have been shown to be safe and cost-effective. However preventive interventions are provided to healthy individuals, most of whom will not suffer any ill effects if the activity is not provided, and a few may suffer adverse effects from the intervention. Failure to identify (Metabolic disease) and prevent (Metabolic disease and VKDB) early in affected individuals can have catastrophic outcomes. In fact, the failure to prevent these conditions could deprive an affected individual from ever achieving his or her own capacity to consent.

In the context of this case, there have not, to my knowledge been any approaches to the Family or High court for a guardianship order to enable a preventive intervention or screening test to be undertaken when parents refuse consent. Given that the probability of harm to the infant arising from the parent's refusal is very low, it is, in my opinion unlikely that such an approach would succeed. The new Public Health

Bill, now out for consultation, canvasses some of the legislative implications around compulsory screening, and interested individuals can access this on the Ministry of Health website: <http://www.moh.govt.nz>.

Under the current legislation I believe best clinical practice would require the identification and acknowledgement of the parents' concerns and assisting them to discern the evidence. Realistic alternatives that protect the child could include:

- providing the parents with reliable written information about early signs of VKDB or metabolic diseases;
- recommending the oral form of vitamin K;
- ensuring that all health practitioners who care for the child are aware of the parents' decision;
- providing regular review of the infant to identify any early signs of these conditions and ensure prompt referral and treatment.

Principles for Practitioners

In the publication on consent (Ministry of Health, 1998) the Ministry of Health identified four principles that will assist in avoiding some of the dilemmas arising and clarify any uncertainties that accompany legislation. The three principles that assist in this case are:

- The best interests of the child should guide all action but not override giving opportunities to children and parents to express their views and have these given due weight.
- Respect and effective communication are the keys to success.
- Ensure that all staff are well informed and guided by policies and comply with legislation and support good practice.
- Confidence and compliance depend on information and support.

Disclaimer:

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Any views expressed in this review are personal to the author and are not necessarily the views of the Ministry, and the Ministry accepts no responsibility or liability in respect of the contents of this review.

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response

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Newborn baby metabolic screening is a very well established preventive public health measure. Canada, North America, Western Europe and Australasia have screened newborns since the 1960s. Most other countries are working towards implementation of universal screening.

Screening is well-proven to be beneficial to infants, preventing severe mental and physical disabilities and saving lives. About 40 New Zealand children per year benefit from screening for seven congenital metabolic disorders (phenylketonuria or PKU, Maple Syrup Urine Disease, galactosemia, biotinidase deficiency, congenital adrenal hyperplasia, congenital hypothyroidism and cystic fibrosis). Screening for these disorders meets the World Health Organisation and other criteria for good screening tests. The test panel used in New Zealand is similar to that used in other countries.

Newborn screening is mandated in all of the United States, separately by state. 23/50 states allow parents to refuse testing on religious grounds and an additional 2 allow refusal on any grounds. In most other places, screening is considered to be an accepted part of healthcare, and consent is not sought. Internationally there is an increasing movement to consumerism in healthcare. As this trend continues, screening programmes are using more, or more formal, consent processes.

Six of the seven disorders tested in New Zealand are of autosomal recessive genetic origin. A number of international studies and reports of genetic testing e.g. the US Taskforce on Genetic Testing agree that parental consent is not necessary where the screening test has been shown to be scientifically valid and clinically useful (i.e. beneficial to the baby) but should be sought for less well-proven screening. Where parental consent is not sought, parents should nevertheless be fully informed about the screening, i.e. information and consent are separable, and information should always be provided.

The Code of Health and Disability Services Consumers' Rights

covers consent. Where the consumer cannot make an informed choice, the Code allows for the choice to be made by someone else. Guardians are legally entitled to consent on behalf of a child (s25 of the Guardianship Act 1968). Where there is no-one available legally entitled to consent on the patient's behalf a healthcare provider can provide services without consent. In that case the services must be in the best interests of the consumer, but if consent is given by a parent there is no such obligation stated.

The argument about whether parents should be able to refuse newborn screening for their child comes down to one of parental autonomy vs the future autonomy of the child. There is no documented framework for weighing the respective merits of the arguments for parents' or child's autonomy.

Policy around children is firmly focused on actions of the community and adults responsible for the care of children being in the best interests of the child. We have legislation which makes some decisions about actions in the best interests of children. As a community we have decided that it is in their best interests if children are restrained in motor vehicles; wear helmets on cycles; do not have free access to swimming pools; be educated in an approved school or to an approved plan, not be left home alone. We have no difficulty in declaring that an individual parent should not have, and does not have, the right to decide whether their child wears a seatbelt or gets an education. In these cases, parental autonomy gives way to the child's future autonomy.

While the probability of an individual child on a particular car journey being involved in an accident is low, if an accident does occur the probability of injury to the child is high and much reduced by the use of an approved child restraint. We use the law to insist parents use restraints. While the probability of an individual child being affected by a congenital metabolic disorder is low (overall about 1:1400), the effects of the disorders are catastrophic and preventable by screening, early diagnosis and treatment. However, parents have a choice

whether their child will have a screening test or not. Our community insists that for health matters, unlike the more social matters referred to above, parents retain the right to make the choices for their children.

It is not acceptable for a parent to expose their child to the risk of brain damage by being unrestrained in a car, or not wearing a cycle helmet, but it is acceptable for them to expose

the child to the risk of brain damage from undiagnosed congenital hypothyroidism or PKU. It may be time for more public discussion of the right of our children to achieve their potential through well proven newborn screening tests.

Disclaimer

The views in this commentary are those of the author and do not necessarily represent those of the National Testing Centre.