

## Legal Issues in Neonatal Screening

J.Gerard Loeber,<sup>1</sup>*degrees*

### Abstract

Legal issues arise if some persons or institutions feel wrongfully treated whether or not this feeling is justified. In neonatal screening, the following topics may be causing legal issues: no screening programme where such a programme should be (UN Convention for the right of the child); neonate(s) not screened for conditions within the established programme; no consent when it should have been given; error(s) in sampling, analysis, reporting; no follow-up available, error(s) in confirmatory diagnostics and treatment; irregular storage of dried blood spot specimen. Legal issues can be solved easily when responsibilities of parties concerned have been established and documented. Unfortunately, legal systems vary from country to country and what has become “normal” practice in one jurisdiction may still be battled about in another. The management of a neonatal screening programme should try to define as best as possible the performance criteria and to have the programme assessed and accredited to certain internationally accepted standards. It diminishes the chances for errors and it helps to avoid legal issues.

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The title of this presentation comprises 2 concepts. Neonatal screening does not need extensive introduction since it has become part of routine public health in many countries around the globe. It consists of a series of events, starting with taking a blood sample from the newborn infant and analysing this sample for one or more components that are indicative of the presence or possible development of a congenital metabolic disorder. If the results indeed point to such disorder, then the child is referred to a paediatrician for confirmatory diagnostics, usually by analysing a venous blood sample, treatment by medication or diet, and eventually, long-term follow up for one to several years to ensure that the child develops as normally as possible with as few deteriorating health effects as possible.

Legal issues is a more difficult concept which can be understood as matters related to the legal system. A legal system is defined in several ways such as an explicit, institutionalised, and complex mode of regulating human conduct, or as a set of rules which influence behaviour. In addition, a legal system is always connected to social and moral rules and finally, there is a relationship between the concepts of law and ethics. Legal issues arise when there is a discrepancy between an individual's presumed rights and

the perceived situation in practice. In other words, identical practical situations may be viewed by one individual as normal whereas another may conclude that his rights are violated and consequently will take legal steps to protect his rights.

To understand when and where legal issues exist or may arise, it is necessary to answer 4 questions:

1. Which rights are valid in a certain situation?
2. Are these rights real or presumed?
3. What is the practical situation in which someone feels unhappy?
4. Is that unhappiness realistic or perceived?

To make this more concrete, let's consider the following examples.

1. A car collision. The person whose car has been hit normally has a right for damage reimbursement, i.e. a real right; if the reimbursement does not take place, he can start a legal procedure.
2. House on fire. Most communities have stipulated the period in which the fire brigade should be present to fight the fire. If the fire brigade is too late, the house owner normally has a right to claim damage reimbursement from the local municipality; again, if the

<sup>1</sup> International Society for Neonatal Screening (ISNS), The Netherlands

Address for Correspondence: Dr Gerard Loeber, International Society for Neonatal Screening (ISNS) and RIVM, PO Box 1, 3720 BA Bilthoven, The Netherlands.  
Email: Gerard.Loeber@rivm.nl

reimbursement does not take place, he can start a legal procedure to enforce his claim.

3. In healthcare the situations may be more difficult. If the surgeon in spite of correct administrative data amputates the wrong leg, the patient can claim damage reimbursement and otherwise he can sue the surgeon. On the other hand, if a smoker gets lung cancer, can he really claim anything from the tobacco company; if he exposes his lungs to cigarette smoke, does he have a real or a perceived right for healthy lungs?

Back to neonatal screening. Can a parent claim the availability of a neonatal screening programme for a certain condition, e.g. phenylketonuria, in his jurisdiction? Can he claim reimbursement if it is not available? Can he argue that his jurisdiction should have the same screening policy as another jurisdiction where screening for phenylketonuria is available? What are his real rights?

In this respect, it is interesting to read the United Nations Convention on the Rights of the Child<sup>1</sup> which was ratified by virtually all UN member states. In Article 24, it reads that “States Parties recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health” and that “States Parties shall strive to ensure that no child is deprived of his or her right of access to such healthcare services”. On the one hand, the text emphasises the right of the child, e.g. to be screened neonatally, and on the other hand, it does not go further than that the States shall strive to achieve this. The parent mentioned above therefore cannot claim anything in this respect.<sup>2-4</sup> He can only try to persuade the politicians in his jurisdiction to make neonatal screening available.

In case there is a neonatal screening programme running, it should stipulate performance criteria such as coverage of the newborn population, timeliness of sampling, analysis and reporting results, availability of treatment, follow-up etc, and last but not least the conditions of storage of dried blood spot specimens and its potential use.<sup>5</sup> In such a

situation, there may be a legal issue if a child is not sampled at all, not sampled within the stipulated time window, results are lost, the child is not referred in time, or the use of the stored specimens for other purposes.<sup>6</sup> Depending on the local organisation the parent can claim damages with the programme management, the person not having taken the sample, the laboratory not having performed the analysis in the prescribed way etc.

In general, the more precise a situation has been defined, the easier it is to determine whether rights are valid and have been violated and the better the chance on success when claiming for damage reimbursement. The management of a neonatal screening programme should try to define as best as possible the performance criteria and to have the programme assessed and accredited to certain internationally accepted standards. It diminishes the chances for errors and it helps to avoid legal issues.

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